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ORIGINAL RESEARCH

COPD screening efforts in primary care: what is the yield?

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Abstract
Introduction: Underdiagnosis of COPD appears to be common, although the degree of underdiagnosis is rarely measured. To document the extent of underdiagnosis in a high risk group of ambulatory patients, we performed spirometry in smokers aged 40 years and over drawn from general practices in two countries.
Methods: Subjects were recruited from primary care practices in Aberdeen, Scotland, and Denver, Colorado, via random mailing. Current and former smokers aged 40 or older with no prior diagnosis of chronic obstructive respiratory disease (and no respiratory medications within the past year) were enrolled. Participants underwent pre- and post-bronchodilator spirometry. A study diagnosis of COPD was defined as post-bronchodilator $FEV_1/FVC < 0.70$.
Results: Spirometric examination was complete in 818 patients, of whom 155 (18.9%) had a study diagnosis of COPD. Using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) severity criteria, the COPD was mild in 57.4%, moderate in 36.8%, and severe in 5.8%. No patients had very severe disease according to GOLD criteria.
Discussion: Screening of smokers over 40 in general practice may yield 10 — 20% undiagnosed COPD cases, with a substantial proportion of these having moderate to severe disease. Earlier diagnosis through targeted case-finding will allow early, aggressive smoking cessation efforts and may lead to a reduction in the burden of COPD symptoms and a reduced impact of the disease on health-related quality of life in these patients.

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Introduction

Chronic obstructive pulmonary disease (COPD) ranks among the top five causes of death in developed countries.[1] COPD also has a major effect on health status, and commonly causes limitation of job activities and other activities of daily living.[2] Unlike other major causes of death and disability which have decreased as a result of medical advances over the last few decades,[3] COPD continues to increase its effects on morbidity and mortality.[4,5]

Smoking is recognized as the most important risk factor for COPD.[2] If COPD is diagnosed early, smoking cessation causes a marked reduction in the irreversible accelerated age-related decline in FEV_1 associated with the disease.[6-8] Although other available therapies do not alter the rate of lung function decline, they have been demonstrated to reduce symptoms, improve functional status, decrease exacerbations, and improve health-related quality of life (HRQOL).[1,9,10] Early identification of COPD is thus critical in order to begin smoking cessation efforts and to institute therapy to reduce the burden of disease on the patient. Delay in diagnosis only prolongs the time period before beginning these activities.

Unfortunately, delay in diagnosing COPD appears common, although the magnitude of this problem has not been well measured. The oft-cited statistic that 50% of COPD is undiagnosed is not well supported with objective evidence.[11] One literature review, which included population-based as well as clinical studies, found prevalence estimates for undiagnosed airway obstruction ranging from 3% to 12%.[12] For clinicians, it may be more important to consider the likely yield of COPD case-finding efforts in general practice.

In order to document the degree of under-diagnosis of COPD in a high risk group of ambulatory patients, we performed spirometry with reversibility testing among smokers aged 40 years and over drawn from general practices in the United Kingdom and United States.

Methods

As part of a larger study of respiratory diagnosis,[13] we recruited subjects from primary care practices associated with the principal investigators' (DBP, DGT) institutions in Aberdeen, Scotland (UK) and Denver, Colorado (USA) by random mailing to individuals aged 40 years and older on the practice lists. Respondents were assessed for eligibility and those who were eligible were enrolled after obtaining ethical approval. We considered participants eligible if they had a positive smoking history (current or former smokers) and reported no prior diagnosis of any chronic obstructive respiratory disease. Persons who had received any respiratory medications within the past year were considered to have an implicit diagnosis, and were excluded. Other exclusion criteria included: refusal to consent or participate; history of known pre-existing or concomitant non-obstructive lung disease (eg, sarcoidosis, tuberculosis, lung cancer); and acute symptoms suggestive of unstable heart disease (eg, chest pain, diaphoresis, œdema, palpitations). We deferred evaluation of subjects with acute respiratory illnesses until the acute episode had resolved.

Spirometry was performed identically at both sites according to procedures recommended by the American Thoracic Society (ATS)[14] using identical EasyOne™ spirometers (ndd Medical Technologies, Andover, Massachusetts and Zürich, Switzerland). Spirometers were calibrated at the beginning of each workday. After the initial procedure, 2.5 mg salbutamol/albuterol was administered via nebuliser mask over 5 to 15 minutes to all subjects. After an additional 15 minutes, post-bronchodilator spirometry was performed. All spirometry loops were blinded and reviewed by both principal investigators for adequacy of effort. A pulmonologist who was not associated with the study reviewed all loops on which there was disagreement between principal investigators.

After data cleaning, subjects were placed into one of four diagnostic categories based on spirometric criteria drawn from the guidelines developed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD).[15] These diagnostic criteria, which are provided in Table 1, are consistent with those recently adopted by the ATS and the European Respiratory Society.[16] All study diagnoses were based on post-bronchodilator spirometry values. Body mass index (BMI) was calculated by dividing the weight in kilograms by the square of the height in meters. Between-group differences were evaluated using Chi-square for categorical variables and 2-sample t-test for continuous variables. All analyses were performed using STATA statistical software package (Release 7.0. StataCorp; College Station, TX, 2001).

Results

Of 1,631 responders to our mailed invitation, 898 were smokers with no prior diagnosis or medications consistent with obstructive lung disease. A satisfactory spirometric examination was

Table 1 Study Diagnoses

Study Diagnosis	Criteria
No COPD	Post-bronchodilator $FEV_1/FVC \geq 0.70$
Mild COPD	Postbronchodilator $FEV_1/FVC < 0.70$ $FEV_1 \geq 80\%$ predicted
Moderate COPD	Postbronchodilator $FEV_1/FVC < 0.70$ $FEV_1 \geq 50\%$ predicted and $FEV_1 < 80\%$ predicted
Severe COPD	Postbronchodilator $FEV_1/FVC < 0.70$ $FEV_1 \geq 30\%$ predicted and $FEV_1 < 50\%$ predicted

COPD = chronic obstructive pulmonary disease; FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity

Table 2 Characteristics of the study population

Characteristic	Variable		Aberdeen (n=401)	Denver (n=417)	Total (n=818)
Demographics	Age in years, mean ± std. dev.*		59.3 ± 11.0	57.1 ± 11.3	58.2 ± 11.2
	Age categories, n (%)*	40 — 49	86 (21.5%)	127 (30.5%)	213 (26.0%)
		50 — 59	131 (32.7%)	124 (29.7%)	255 (31.2%)
		60 — 69	100 (24.9%)	98 (23.5%)	198 (24.2%)
		70+	84 (21.0%)	68 (16.3%)	152 (18.6%)
	Male, n (%)		202 (50.4%)	201 (48.2%)	403 (49.3%)
	Body mass index, mean ± std. dev		28.3 ± 5.4	28.3 ± 6.0	28.3 ± 5.7
Smoking	Status, n (%)	Former	214 (53.4%)	240 (57.6%)	454 (55.5%)
		Current	187 (46.6%)	177 (42.4%)	364 (44.5%)
	Pack-years, mean ± std. dev.*		28.6 ± 22.5	22.8 ± 25.7	25.6 ± 24.3
	Pack-year categories, n (%)*	0 — 14	111 (27.7%)	174 (41.7%)	285 (34.8%)
		15 — 24	81 (20.2%)	84 (20.1%)	165 (20.2%)
		25 — 49	147 (36.7%)	123 (29.5%)	270 (33.0%)
		50+	62 (15.5%)	36 (8.6%)	98 (12.0%)
Pulmonary function (post-bronchodilator values)	FEV_1, mean percent of predicted		93.4%	95.6%	94.4%
	FVC, mean percent of predicted		95.3%	96.3%	95.8%
	FEV_1 /FVC, mean (range)		0.75 (0.36-1.00)	0.77 (0.35-0.97)	0.76 (0.35-1.00)

FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity
* Difference between sites $P < 0.005$

completed in 818 of these subjects, 401 in Aberdeen and 417 in Denver. These subjects are described in Table 2. The average age was 58.5 years, and 49.3% were male. Just under half of the sample (45%) were current smokers at the time of interview. Respondents in Aberdeen were significantly older and had more pack-years of smoking exposure than Denver respondents.

Table 3 describes the characteristics of the 155 patients who received a study diagnosis of COPD out of the total 818 subjects studied — a prevalence of 18.9%. Compared with the study population as a whole, patients with COPD were more likely to be older, to have a lower BMI, to have more pack-years of smoking exposure, and to be male. Using the GOLD criteria, the COPD severity was mild in 57.4%, moderate in 36.8%, and severe in 5.8%. There were no patients with very severe disease by GOLD criteria (i.e., FEV_1 <30% predicted). There were small differences

Table 3 Characteristics of persons with previously undiagnosed COPD

Characteristic	Variable		Mild COPD	Moderate COPD	Severe COPD	Total COPD
			$FEV_1 \geq 80\%$ predicted	$FEV_1 < 80\%$ predicted AND $FEV_1 \geq 50\%$ predicted	$FEV_1 < 50\%$ predicted AND $FEV_1 \geq 30\%$ predicted	Postbroncho-dilator FEV_1 /FVC < 0.70
			n=89 (57.4%)	n=57 (36.8%)	n=9 (5.8%)	n=155 (100%)
Demographics	Age in years, mean ± std. dev		64.6 ± 11.3	64.0 ± 9.6	62.9 ± 7.7	64.3 ± 10.5
	Age categories, n (%)	40 – 49	11 (12.4%)	4 (7.0%)	–	15 (9.7%)
		50 – 59	17 (19.1%)	16 (28.1%)	3 (33.3%)	36 (23.2%)
		60 – 69	28 (31.5%)	19 (33.3%)	3 (33.3%)	50 (32.3%)
		70+	33 (37.1%)	18 (31.6%)	3 (33.3%)	54 (34.8%)
	Male		62 (69.7%)	29 (50.9%)	5 (55.6%)	96 (61.9%)
	Body mass index, mean ± std. dev		26.8 ± 6.0	27.1 ± 4.9	27.1 ± 6.2	26.9 ± 5.6
Smoking	Smoking status, n (%)	Former	46 (51.7%)	27 (47.4%)	2 (22.2%)	75 (48.4%)
		Current	43 (48.3%)	30 (52.6%)	7 (77.8%)	80 (51.6%)
	Pack-years, mean ± std. dev		39.9 ± 43.5	37.8 ± 27.0	35.7 ± 27.7	38.9 ± 37.2
	Pack-year categories, n (%)	0 – 14	17 (19.1%)	10 (17.5%)	2 (22.2%)	29 (18.7%)
		15 – 24	17 (19.1%)	8 (14.0%)	2 (22.2%)	27 (17.4%)
		25 – 49	32 (36.0%)	27 (47.4%)	2 (22.2%)	61 (39.4%)
		50+	23 (25.8%)	12 (21.1%)	3 (33.3%)	38 (24.5%)
Pulmonary function (post-bronchodilator values)	FEV_1, mean percent of predicted		92.9%	69.2%	44.7%	80.7%
	FVC, mean percent of predicted		106.1%	83.7%	69.2%	95.1%
	FEV_1 /FVC, mean (range)		0.65 (0.35-0.69)	0.63 (0.44-0.69)	0.50 (0.36-0.62)	0.64 (0.35-0.69)
Site	Aberdeen, n (%)		47 (52.8%)	34 (59.7%)	7 (77.8%)	88 (56.8%)
	Denver, n (%)		42 (47.2%)	23 (40.4%)	2 (22.2%)	67 (43.2%)

COPD = chronic obstructive pulmonary disease; FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity

between severity groups but these were not statistically significant.

Discussion

Our results suggest that a substantial proportion of smokers over 40 in general practice have undiagnosed airway obstruction consistent with the most widely accepted definition of COPD. Furthermore, many of these patients have moderate to severe disease.

Why is this fatal disease so often missed? Firstly, it is likely that many physicians are not fully aware of the importance of symptoms and risk factors for COPD. One study of 455 doctors showed that only half of physicians used spirometric criteria to define COPD, and only one third knew the correct GOLD criteria.[17] This study and others like it suggest that there are major gaps in the knowledge of all the core elements of guidelines for the management of COPD. Secondly, patients tend to adapt to the insidious onset of COPD symptoms, seeking medical advice only when symptoms affect their quality of life.[18] It has been suggested that a substantial minority of patients

with COPD are relatively impaired in their ability to perceive dyspnœa, which would further delay their presentation for treatment.[19] In extreme cases, patients do not come to diagnosis until their hospitalisation for an acute exacerbation, by which time considerable loss of ventilatory reserves has already occurred.[20]

Clearly, waiting for patients to present with classic symptoms of cough, sputum and dyspnœa is not a robust approach. For this reason, more active approaches have been advocated.[21] For the primary care physician, recommended approaches centre around efforts directed at patients already in the practice, although the cost effectiveness of opportunistic case-finding is still under debate.[22] Certainly, these case-finding activities should not impose an undue burden in terms of cost or time. In addition, we believe that primary care practices are unlikely to persist in outreach efforts to identify COPD unless at least two conditions are in place: firstly, case-finding efforts should produce an acceptable yield of new cases; and secondly, there should be some meaningful interventions to offer newly identified cases.

Our results are subject to some limitations. Although we mailed to a random sample of patients from the general practice lists, our response rates were relatively low (6-24%). These are within expected ranges for a single unsolicited mailing. And since we mailed to all people 40 or older, 'never smokers' would not have responded, making it impossible to determine our true response rate. Currently available information suggests that estimated (current) smoking rates are 30-32% in Scotland[40] and 40.5-52.5% (current and former smokers) in Colorado.[41] Applying these rates to our sampling frame suggests our response rates among smokers were probably closer to 10% in Denver and 75% in Aberdeen. Nevertheless, we believe our respondents fairly represent those likely to come forward for case-finding in primary care. For non-responders, different approaches may be necessary — for example, a more personalised invitation or a more specifically targeted message might encourage better participation.

Our study relied upon data collected at a single clinic visit. Thus, despite our use of post-bronchodilator spirometry to assess obstruction, it is possible that a small proportion of patients with seemingly irreversible airway obstruction would have returned to normal with a course of inhaled steroids, suggesting the possibility of asthma as a diagnosis. However, we believe undiagnosed asthma is an unlikely explanation for our findings in these previously undiagnosed smokers, as they were responding to a mailed invitation and not presenting with respiratory complaints. In addition, we excluded patients taking respiratory medications but with no previous respiratory diagnosis. Including these patients in the study would have increased the prevalence of undiagnosed COPD slightly.

Underdiagnosis: prevalence or yield?

A recent review estimated the prevalence of undiagnosed airway obstruction (including COPD and asthma) at between 3% and 12%.[12] Recent population-based studies from Greece, Korea and Sweden have produced underdiagnosis estimates consistent with this range.[23-25] However, a more relevant question for the physician may be "what is the likely yield of case-finding efforts in my practice?" Our results are consistent with the relatively few studies carried out among high risk groups in general practice settings (Table 4). These studies suggest that case-finding efforts focused on at-risk patients in a general practice setting can yield up to 10-20% new cases. Using random mailing to general practitioner (GP) lists, Renwick and Connolly found chronic airways obstruction in 26.4% of people aged 45 and older, 55% of whom did not have a previous diagnosis.[26] They found higher rates of obstruction in current smokers (39.7%) and former smokers (27.7%), but did not report how many of these patients had prior diagnoses. Dickinson *et al*. uncovered 22 new cases of COPD among 353 men and women aged 60-75 years randomly selected from a general practice register, a yield of 6.2%.[27] By focusing on case-finding in smokers aged 35-75, van Schayck and colleagues found that 18% had airflow obstruction.[28] Takahashi *et al*. performed screening spirometry on 1,040 smokers over age 40 years drawn from 56 hospitals and general practices in Japan, finding airway obstruction in 27%;[29] a diagnosis of COPD was confirmed by a physician in 81% of these, yielding 21% new cases. Buffels and colleagues invited patients aged 35-70 to complete a short questionnaire followed by spirometry;[30] they estimated that 7.4% of these patients had undiagnosed obstructive lung disease, although they did not distinguish between asthma and COPD.

Results from voluntary screening programs administered to general populations have shown even higher prevalence figures — above 20% — for undiagnosed COPD. Zielinski and colleagues found airway obstruction in 24.3% of adults volunteering for spirometry in 12 cities in Poland,[31] and among 4,669 smokers over age 39 years, the rate of undiagnosed obstruction was 29.3%. In a similar study carried out in Sweden, Stratelis *et al*. advertised free spirometry to smokers aged 40-55

Table 4 Undiagnosed COPD in general practice settings

Study	Study Population (Age)	Diagnostic criterion	N	COPD (%)	Undiagnosed COPD (%)	Severity distribution	
						Mild	Moderate-Severe
Renwick and Connolly (1996)[26]	45+	$FEV_1/FVC < 65\%$ (age < 65 years); $FEV_1/FVC <$ lower limit of normal (age 65+)	247	26.4%	14.5	66% *	34% *
Dickinson, *et al.* (1999)[27]	60—75	FEV_1 < lowest quintile; FEV_1 reversibility < 9% predicted	353	9.9	6.2	—	—
van Schayck, *et al.* (2002)[28]	35—70, smokers	FEV_1 < 80% predicted	169	18.0	18.0	—	—
Takahashi, *et al.* (2003)[29]	40+, smokers or respiratory symptoms	$FEV_1/FVC < 70\%$ predicted	1,040	27.0	21.9	39.2%†	60.8%†
Buffels, *et al.* (2004)[30]	35—70	$FEV_1/FVC < 88.5\%$ predicted (men); $FEV_1/FVC < 89.3\%$ predicted (women)	3,158	7.4%‡	7.4%‡	39%†	61%†
Current study (2005)	40+, smokers	Postbronchodilator $FEV_1/FVC < 70\%$	818	18.9	18.9	57.4%†	42.6%†

COPD = chronic obstructive pulmonary disease; FEV_1 = forced expiratory volume in one second; FVC = forced vital capacity

* Mild = $FEV_1 \geq 60\%$ predicted; moderate-severe = $FEV_1 < 60\%$ predicted

† Severity determined according to GOLD criteria: Mild = $FEV_1 \geq 80\%$ predicted; Moderate-Severe = $FEV_1 < 80\%$ predicted[15].

‡ This report did not distinguish between asthma and COPD.

years.[32] Using earlier ERS diagnostic criteria (FEV_1/VC <88% predicted in males and <89% predicted in females), they found undiagnosed COPD in 27%. It is most likely that these high rates are the result of selection bias, as these types of programs tend to attract persons with a prior interest.

Why does early diagnosis matter?

Firstly, early and aggressive attempts to stop smoking are the only hope these patients have for preserving lung function. As per the well-known Fletcher-Peto diagram, the higher on the FEV_1 curve the diagnosis occurs, and the earlier any intervention, the better the opportunity for lung preservation.[33] Current thinking recognizes smoking as a relapsing chronic disease and not purely a lifestyle choice.[9] Cessation is thus regarded as remission induction, and relapse is approached using secondary quit attempts ('reinduction') repeated as often as necessary.[34] This model, which is supported by a broad base of scientific evidence,[35] prescribes intensive prolonged efforts in smokers, and suggests beginning the process as early as possible. Half of our respondents with undiagnosed COPD identified themselves as former smokers. The chronic disease model would suggest that these smokers are in remission, and that close follow-up to prevent or treat relapse is appropriate.

Secondly, early diagnosis facilitates targeted warnings about the dangers of smoking, which may be more effective than general "stop smoking" advice. In a randomised intervention, Risser and Belcher showed that smokers who receive physiological evidence such as spirometry results, exhaled carbon monoxide measurements and the presence of pulmonary symptoms, are more than twice as likely to quit when given smoking cessation education.[36] Similarly, Humerfelt and colleagues found that person-specific information mailed to smokers with a decreased FEV_1 and a history of

asbestos exposure led to markedly increased quit rates at one year.[37] In their follow-up of 3,077 smokers participating in a spirometric screening program, Bednarek and colleagues concluded that a diagnosis of airflow limitation motivated smokers to attempt to quit.[38] Conversely, it may be that smokers with COPD are less amenable to intervention than the general population, which would weaken the importance of screening.

Finally, earlier diagnosis allows a reduction in the burden of COPD on the patient through appropriate symptomatic pharmacotherapy, prevention of exacerbations, and pulmonary rehabilitation.[9] Over 40% of our respondents with undiagnosed COPD had obstruction rated as moderate or severe by GOLD criteria, the categories of patients for whom therapy is most commonly recommended as being appropriate.[1,9,10] Our findings are consistent with those described by Takahashi[29] and Buffels,[30] who found over 60% of undiagnosed cases with moderate to severe disease. Undiagnosed airflow obstruction is associated with impaired health and functional status.[39] Undiagnosed disease is also likely to impact on days missed from work due to untreated symptoms. Given the HRQOL impact on these patients, therapeutic nihilism must be condemned. Early appropriate therapy is the only ethical option.

Conclusions

Up to 10-20% of smokers over 40 years of age in general practice may have undiagnosed COPD, and a substantial proportion of these have moderate to severe disease. Earlier diagnosis through targeted case-finding will allow early, aggressive smoking cessation efforts and may lead to a reduction in the burden of COPD symptoms and a reduced impact of the disease on HRQOL in these patients.

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Conflicts of Interest

DGT is an employee of the National Jewish Medical and Research Center which received funding from Boehringer Ingelheim to participate in this study.

DBP has received honoraria for speaking at sponsored meetings and serving on advisory panels for the following companies marketing COPD products: AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Novartis, and Pfizer. He or his research team have received funding for research projects from the following companies marketing COPD products: AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Novartis, and Pfizer.

At the time this study was performed, RJN and RJH were employees of Protocare Sciences which provided consulting services to the pharmaceutical industry, including the sponsors of this study.

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