Detection of Chronic Obstructive Pulmonary Disease in Primary Care in Salzburg, Austria: Findings from the Real World

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Key Words

Airway obstruction · Chronic obstructive pulmonary disease · Epidemiology · Primary care · Spirometry

Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a major public health burden and profoundly affects individuals suffering from the disease. However, the majority of subjects with COPD are still undiagnosed. **Objectives:** To evaluate COPD prevalence and detection strategies for COPD in the primary-care setting. **Methods:** The study was conducted in a random sample of general practitioner (GP) offices in Salzburg (Austria). A questionnaire and post-bronchodilator (PBD) spirometry was administered to patients aged ≥ 40 years. Nonreversible airway obstruction was considered when PBD FEV_1/FVC was < 0.70 . Severity of spirometrically defined COPD was graded according to the GOLD recommendations. **Results:** 60 GP offices were randomly selected for study participation, however only 30 (50.0%) were willing to participate. 1,230 of 9,820 (12.52%) patients consented to the protocol. Quality of PBD spirometry was evaluated, and 882 (71.7%) met ATS/ERS quality criteria. 7.5% (95% CI: 5.7–9.4%) of the patients had COPD grade II+ ($FEV_1/FVC < 0.7$ and $FEV_1 < 80\%$ of predicted), but only 22.4% of them reported a prior physician's diagnosis of COPD. Similar

results were seen for the 2005 Salzburg BOLD (Burden of Obstructive Lung Disease) sample with regard to COPD GOLD II+ prevalence (10.7%) and proportion of underdiagnosis (82.3%). **Conclusion:** COPD in the primary-care setting is as prevalent and underdiagnosed as reported recently for the BOLD study. The surprisingly low participation rate of GPs and patients indicates that prevention of COPD is not a health priority, and that awareness for COPD has to be heightened before case-finding strategies will be successful.

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Introduction

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of mortality globally and was projected to rank third by 2020 [1]. Even in developed countries, where the prevalence of smoking has been stable or slightly decreasing, the prevalence of COPD will rise due to the aging of these populations. For Austria, we estimated a 24% age-related increase in COPD prevalence for 2010–2020 [2].

The international population-based PLATINO (Proyecto Latino Americano de Investigación en Obstrucción Pulmonar) and BOLD studies performed post-bronchodilator (PBD) spirometry in a highly standard-

ized manner, and reported COPD GOLD II+ prevalence between 7.8 and 22.2% for participating countries [3, 4]. Publication of the PLATINO and the BOLD prevalence data strengthened the cause for COPD as a public health priority [5]. Given that the majority of patients with COPD are seen in primary care, early detection and prevention of COPD will have to be performed in this setting.

The diagnosis of early airway obstruction indicating COPD requires high-quality spirometry to detect even minor obstructions with confidence [6] since low-quality spirometry will either cause false-positive COPD diagnosis or miss patients with obstructive disease. In this way, low-quality spirometry will harm subjects with a false-positive COPD diagnosis and increase health care costs for treatment of nonexistent disease. On the other hand, windows of opportunity for smoking cessation to stop further loss of lung function might be missed when early COPD goes undetected. The issue of the quality of spirometry in the detection of COPD in primary care has been discussed recently [7], but it is not yet clear whether spirometry should be done in primary-care practices or spirometry services should be offered to GPs [8, 9].

Another controversy surrounding the issue of detection of early COPD relates to the population which should be targeted with spirometry [10]. While opportunistic population screening has been advocated in the past [11, 12], the discussion has now moved towards targeted screening and case finding [13]. Despite these open issues, a recent nationwide primary care-based COPD program has been successfully completed in Finland, which demonstrated that increased use of spirometry over 10 years can reduce COPD exacerbations, hospitalizations and associated health care costs [14].

Given these uncertainties, we followed the highly standardized BOLD protocol in patients from GP offices from the county of Salzburg, Austria. These data should help to elucidate whether the strictly population-based BOLD data can be used to estimate COPD prevalence in primary-care offices, and whether such a protocol would be feasible in this setting. A selection bias and potential overuse of primary-care services by healthy subjects has been seen with other diseases [15], and, if also present for COPD, would possibly hinder detection and prevention efforts.

Methods

Data Collection

Primary-care practices were contacted in cooperation with the medical association of the county of Salzburg. A list of all 159 general practitioners (GPs), who had a full contract with the local

health insurance, was provided, and a random sample of 60 GPs was chosen. No formal sample size calculation was performed; however, we assumed that this sampling strategy would result into a sample size comparable to the BOLD sample [13]. We deliberately decided to use a random sample of primary-care practices to obtain a real-world picture of the willingness and feasibility of COPD detection.

The study was carried out from the beginning of September until the end of December 2007. A minimum of 2 weeks of data collection was planned for each participating GP office. On study days, all attending patients aged 40 and older were invited to participate by the physician, his/her assistant and/or a member of our study team. The purpose of spirometry was explained and informed consent was obtained from all patients. The Ethics Committee of the county of Salzburg approved the study.

PBD Spirometry

Spirometry was performed according to ATS/ERS guidelines [16] by trained and certified technicians using the ndd Easy One™ spirometer (ndd Medizintechnik, Zürich, Switzerland). Measurements were performed in a seated position, prior and 15 min after bronchodilation (two puffs of 200 µg salbutamol with a Volumatic Spacer; GlaxoSmith-Kline; Research Triangle Park, N.C., USA). To ensure and maintain quality of spirometry, pulmonary physicians (B.L. and L.S.) evaluated the readings on a daily basis. When the quality of those readings dropped below a preset level, technicians had to stop conducting spirometries and were retrained and recertified by lung function technicians. Spirometry data which did not meet ATS/ERS quality criteria were not included in the final data analysis [16].

To be acceptable, spirometry data had to meet the following three quality criteria: (1) patients had to perform at least three trials; (2) at least two of the three trials were acceptable (no artifacts, no sudden stops and a back extrapolated volume $\leq 5.0\%$ of the FVC), and (3) reproducible values for FEV₁ and FVC (the difference between the highest and the second highest reading has to be <200 ml).

Questionnaire Data

Information on the patients' demography and medical history was collected using the BOLD questionnaire, which includes questions on respiratory symptoms, COPD risk factors, quality of life, medication, reported physician's diagnosis of COPD and limitation of activities [17].

Definitions

Nonreversible airway obstruction was defined as a PBD FEV₁/FVC ratio <0.70 . The grading of severity of spirometrically defined COPD followed the GOLD guidelines: GOLD grade II was defined as FEV₁/FVC <0.70 and FEV₁ predicted between 50 and 80%; GOLD grade III–IV was defined as FEV₁/FVC <0.70 and FEV₁ predicted $<50\%$ [18]. The predicted values were calculated using the NHANES III data [19]. A prior physician's diagnosis of COPD was considered present when a positive answer to diagnosed chronic bronchitis, diagnosed emphysema or diagnosed COPD was reported.

Study participants were classified as ever smoker when they had smoked at least 20 packs of cigarettes in their life or more than 1 cigarette per day for 1 year. The cumulative burden of smoking was defined as pack-years, which is the mean number of cigarettes

Table 1. Participation in GP offices from Salzburg, Austria

Primary care office	Study duration, weeks	Patients >40 years, n	Study participants, n	Participation rate, %
1	3	1,914	102	5.3
2	3	682	78	11.4
3	3	405	76	18.8
4	3	356	61	17.1
5	1	191	19	9.9
6	3	301	145	48.2
7	3	713	65	9.1
8	3	555	115	20.7
9	1	110	11	10.0
10	5	1,075	145	13.5
11	2	144	18	12.5
12	4	987	65	6.6
13	2	287	35	12.2
14	3	191	41	21.5
15	2	251	43	17.1
16	2	308	34	11.0
17	2	433	53	12.2
18	2	309	48	15.5
Subtotal	2.6	9,212	1,154	12.5
19 ^a	2	304	38	12.5
20 ^a	2	304	38	12.5
Total	51	9,820	1,230	12.5

^a We had no information on the total number of patients seen, therefore the mean overall participation rate was assumed.

on average smoked per day divided by 20 times the duration of smoking years. Willingness to quit was assumed when smokers reported that they seriously wanted to give up smoking within the next 6 months.

Statistical Analysis

For data analysis, SAS version 9.1 was used. The t test for independent samples, the χ^2 test and the nonparametric Mann-Whitney U test were applied. Some of the study data were also compared with the results of the Austrian BOLD study [13].

Results

Study Participation and Quality of PBD Spirometry

Sixty GP offices were randomly selected for study participation, but only 30 (50.0%) were willing to participate. When contacted, the following reasons for nonparticipation were given: 'I do not have enough space to conduct spirometry' (n = 11); 'I have no interest' (n = 7); 'I have too much work' (n = 4); 'the study will disturb my daily

Fig. 1. Flow chart of the study population.

routine' (n = 3), and 'I am working only as a dentist' (n = 1). Four offices could not be contacted although several attempts were made by telephone. Ten GP offices wanted to participate but could not be included because of study termination. GP offices were well distributed between urban and rural areas in the county of Salzburg. These offices are organized as single (not group) practices and the GPs are assisted by trained nurses. Spirometry in primary care is, however, not reimbursed to support COPD detection and prevention in this area.

At each of the 20 participating GP offices, between 1,914 and 110 patients were seen, and between 5.3 and 48.2% of them agreed to participate (table 1). Altogether, 1,230 patients participated, and 1,081 (87.8%) completed the questionnaire and PBD spirometry (fig. 1).

However, only 71.7% of PBD spirometry readings met ATS/ERS quality criteria [16]. Spirometry test failures were as follows: 97 patients recorded only one or two PBD trials, and in 108 patients acceptability criteria and in 101 patients repeatability criteria were not met (fig. 1). Given the high

Table 2. The distribution of age, gender and nonreversible airway obstruction (AO: FEV₁/FVC <0.7) according to quality criteria for PBD spirometry

	Criterion present	Criterion absent	p value
<i>At least three trials</i>			
Patients (1,081), n	984	97	
Age (mean ± SD), years	59.4±0.36	55.4±1.05	<0.001
Male gender, %	42.7	44.3	NS
AO (FEV ₁ /FVC <0.7), %	17.2	15.5	NS
<i>At least two acceptable trials</i>			
Patients (984), n	876	108	
Age (mean ± SD), years	58.6±0.37	66.5±1.03	<0.001
Male gender, %	44.2	30.6	NS
AO (FEV ₁ /FVC <0.7), %	17.3	15.7	NS
<i>Repeatable FEV₁ and FVC</i>			
Patients (876), n	775	101	
Age (mean ± SD), years	58.4±0.40	59.8±1.09	NS
Male gender, %	41.8	62.4	<0.001
AO (FEV ₁ /FVC <0.7), %	16.8	21.8	NS

Table 3. Characteristics of participating patients with good quality PBD spirometry (n = 775)

Characteristics	Male	Female	Total	p value
Sex	324 (41.8%)	451 (58.2%)	775 (100%)	<0.001
Age (mean ± SD), years	59.0±0.63	58.1±0.52	58.5±0.40	NS
Smoking status				
Current smoker	51 (15.7%)	56 (12.4%)	107 (13.8%)	<0.001
Willingness to quit	35 (68.6%)	24 (60.7%)	0.69 (64.5%)	<0.393
Former smoker	135 (41.7%)	100 (22.2%)	235 (30.3%)	
Never smoker	138 (42.6%)	295 (65.4%)	433 (55.9%)	
Education				
<8 years	35 (10.8%)	82 (18.2%)	117 (15.1%)	0.02
8–12 years	262 (80.9%)	333 (73.8%)	595 (76.8%)	
>12 years	27 (8.3%)	36 (8.0%)	63 (8.1%)	
Prevalence of COPD (GOLD II+)	40 (12.3%)	18 (4.0%)	58 (7.5%)	<0.001
Reported diagnosis of COPD	19 (5.9%)	37 (8.2%)	56 (7.2%)	0.215

Numbers of patients are shown except for age.

spirometry quality failure rate, we analyzed the relationship between spirometry quality failure and presence of airway obstruction. The prevalence of COPD GOLD II+ was not significantly different between those who met and those who failed ATS/ERS quality criteria, indicating that the presence of airway obstruction itself was not related to the quality of spirometry (table 2). Except for age, patient characteristics did not differ significantly between those who met quality criteria and those who did not.

Characteristics of the 775 Participants with Good Quality Spirometry

A greater proportion of female (58.2%) than male (41.8%) patients completed the study protocol, and the majority of patients (55.9%) reported that they had never smoked (table 3). Among current smokers, 64.5% reported their willingness to quit, and a prior physician's diagnosis of COPD was reported in 56 (7.2%) of all participants.

Table 4. Comparison of subjects with COPD GOLD II+ (FEV₁/FVC <0.7 and FEV₁ <80% of predicted) in the GP sample and the BOLD sample

	GP (n = 58)	BOLD (n = 119)	p value
Age (mean ± SD), years	63.9±12.1	65.4±11.4	0.496
Sex			0.106
Male	40 (69.0%)	67 (56.3%)	
Female	18 (31.0%)	52 (43.7%)	
Smoking status			0.630
Current smoker	14 (24.1%)	34 (28.6%)	
Willingness to quit	10 (65.1%)	9 (45.7%)	0.002
Former smoker	24 (41.4%)	52 (43.7%)	
Never smoker	20 (34.5%)	33 (27.7%)	
Education			0.770
<8 years	18 (31.0%)	34 (28.6%)	
8–12 years	36 (62.1%)	73 (61.3%)	
>12 years	4 (6.9%)	12 (10.1%)	
Reported diagnosis of COPD	13 (22.4%)	21 (17.7%)	0.450

Numbers of patients are shown except for age.

Prevalence of Spirometrically Defined COPD

In this primary-care sample, the overall prevalence of COPD GOLD stage I+ was 16.6% (95% CI: 13.9–19.3%). For COPD GOLD stage II+, the prevalence was 7.5% (95% CI: 5.7–9.4%); 4.0% in women and 12.3% in men. The prevalence of COPD GOLD II+ was as expected higher in smokers (13.1%) and former smokers (10.2%) when compared to never smokers (4.6%; $p < 0.01$). Of the 775 patients, 56 reported a prior physician's diagnosis of COPD. This COPD diagnosis was confirmed by PBD spirometry in only 13 patients, indicating a 76.8% false-positive rate.

Comparison of COPD Patients in the Primary-Care Sample and the Austrian BOLD Sample

There was no significant difference in the prevalence of COPD GOLD II+ between the GP sample (7.5%) and the BOLD sample (10.7%) from the same area. Reported COPD diagnoses were also in the same range (BOLD sample: 17.7%; GP sample 22.4%). Subjects with COPD GOLD II+ in the two samples were comparable with regard to age, gender and smoking status (table 4). However, the willingness to quit smoking was somehow higher in GP patients with COPD GOLD II+ (65.1%) when compared to the 2005 BOLD participants (45.7%).

Discussion

We report COPD detection in a random sample of GP offices in Salzburg, Austria. The participation of GP offices, the participation of patients attending these offices, and the quality of spirometry was investigated. This study evaluated the primary-care setting in Salzburg for COPD detection.

Participation of GPs

Only every other GP of those invited was willing to participate. Although spirometry and patient interviews were done by the study team, several reasons for nonparticipation were still brought forward. We purposely selected GP offices at random to minimize selection bias possibly related to the motivation of GPs. The resulting 'real-world' picture tells us that the awareness of GPs for COPD as a preventable disease has to be markedly increased before a reasonable number of GPs will participate in COPD detection. International data indicate that COPD awareness is 70% in the US but only 17% in Germany [20, 21]. This low level of COPD awareness in Germany can also be assumed for Salzburg, which might be one explanation for the low participation of GPs.

Participation of Patients Attending GP Offices

The participation rate varied greatly (between 5.3 and 48.2%) among the participating GP offices depending on the organizational circumstances and the physician's or her/his assistant's motivation to invite patients to the study. Patients' most frequent reasons mentioned for not participating were 'feeling too sick', 'no time' and/or 'no interest'. The mean participation rate was only 12%, which was most likely a consequence of our opportunistic detection strategy, i.e. asking every forthcoming patient to have PBD spirometry. This opportunistic strategy was chosen to avoid a 'healthy participation' bias. As a result, the observed participation rate was well below of what is regarded a successful screening program [22], and other studies on COPD detection have reported higher participation rates [23].

We assume, that participation rates will be greatly increased when patients are informed about the importance of spirometry tests and when participants are preselected for spirometry either because of respiratory symptoms or risk factors [24, 25]. Such a targeted COPD detection strategy will also avoid oversampling of persons at low risk for COPD. In our survey, participation was higher in females than males, and higher in never than ever smokers, indicating that the efficacy of COPD detection can be

increased. Higher participation rates of females have also been reported in other studies conducted in primary-care practices [26–32].

Based on our experience, we argue that explicit appointments for the purpose of COPD detection should be made with patients preselected on the basis of a pre-screening questionnaire [33]. It can be assumed that the majority of patients seek their GP because of an acute or chronic health problem other than nondetected COPD. These patients are therefore not willing to spend extra time in the GP office to undergo spirometry. Targeted spirometry and invitation of participants to scheduled visits are key issues for a successful and efficient COPD detection program, while opportunistic case finding running in parallel with routine care cannot be recommended.

Quality of Spirometry

In our study, 28.3% of spirometry readings had to be excluded because quality did not meet ATS/ERS standards. This quality failure rate was much higher than that observed in the BOLD study, where only 3% of readings failed the same criteria [34]. For other studies on COPD detection in primary care, quality standards were not met in 8–40% of participants [23–25, 35, 36]. The current ATS/ERS quality criteria have been criticized as being too stringent for spirometry in primary care, and older, more disabled patients are often not able to perform a spirometry test of sufficient quality [16]. However, detection of early COPD requires greater precision than diagnosis of more advanced disease.

It is a matter of current debate whether spirometers should be in the hands of GPs, who are busy with numerous other health tasks and possibly perform spirometry only a couple of times a week [8]. However, the 10-year Finnish COPD program has proven that detection can be successful in primary care [14] when greater specialization of GPs is possible and community nurses provide spirometry for several offices.

Even in our study where spirometry was done by qualified technicians, quality was lower than expected, which was attributed to the poor health and/or time constraints of participants [37]. We therefore recommend that targeted spirometry in primary care should be highly standardized and predefined time slots for spirometry should be available. We also analyzed the relationship between spirometry test failure and presence of COPD. We noticed that the presence of airway obstruction itself was not associated with the failure of test quality criteria. Another recommendation for COPD detection would be that spi-

rometry readings of 'low' quality but indicating airflow limitation should not be discarded as nondiagnostic, but should be repeated during subsequent office visits.

Prevalence of COPD

For primary-care practices in the county of Salzburg, a 7.5% prevalence of spirometrically defined COPD GOLD grade II+ was shown. This prevalence was somehow lower but within the range found in our previous finding from the BOLD sample [13]. Further analysis of a data set combining the current primary-care data and the Salzburg BOLD data showed no significant difference between the two samples with regard to COPD risk factors age, gender and smoking status. When COPD prevalence was adjusted for these risk factors in a multivariate model, a lower COPD prevalence was seen for the primary-care sample (data not shown). This difference likely indicates a health-related bias for subjects attending GP offices and a higher prevalence of COPD for the strictly population-based BOLD sample.

In the past, different COPD prevalence estimates have been reported from samples of the same region. For the BOLD study conducted in Poland, a 22.1% COPD prevalence was reported [3], while a study conducted in primary-care practices reported a COPD prevalence of only 9.3% [23]. Both samples were comparable regarding the age distribution and the proportion of never smokers. For Brazil, opposite findings were reported: for general practices COPD prevalence was 25.4% but only 15.8% for a population-based sample [4, 24]. A population study in Japan demonstrated a COPD prevalence of 19.9% whereas a study conducted in primary care reported a prevalence of 27% [38, 39]. Overall, neither the literature nor the findings from our study provide sufficient information to explain these differences in COPD prevalence rates.

Study Limitations

In general, methods, spirometry and the questionnaire used in this study were the same as in the PLATINO/BOLD protocol. However, comparisons of this sample with population-based samples as the BOLD study have to be interpreted with caution due to the low participation rates of GPs and patients, and the high proportion of spirometry tests which did not meet quality criteria. For bronchodilation, only 200 µg salbutamol were used instead of the 400 µg albuterol/salbutamol proposed by current guidelines [40]. This dosage of salbutamol might have overestimated COPD prevalence, but was chosen to be in accordance with the previously used PLATINO/BOLD protocol.

Another limitation of our study was the possible misdiagnosis of COPD, when in fact patients were suffering from asthma. When analyzing our data in this regard, we found that 19.1% of those with COPD stage II+ reported to have asthma. We assume that as COPD has poor public term recognition in Austria, more of the patients who report to have asthma in fact suffer from COPD. Furthermore, there is a well-recognized clinical overlap between the two diseases. Taken together, we presume that this possible misdiagnosis of COPD had no substantial effect on our results.

The point of view of COPD screening has changed in the last decade, and nonselected screening is now regarded inefficient and unjustified [9]. We therefore conclude that nontargeted spirometry offered during routine office time is not an effective strategy and propose the following ways to enforce successful COPD case finding in primary care:

(1) Awareness of COPD has to be heightened in GPs and patients.

(2) Subjects should be preselected for spirometry based on symptoms and risk factors.

(3) Specific appointments should be made to perform spirometry for COPD detection.

(4) Spirometry testing should always be accompanied with quality management.

Randomized trials are under way to more clearly define the strategy to reduce underdiagnosed COPD (www.clinicaltrials.gov; NCT01237561 and NCT01576068). Since COPD causes an enormous burden on society but also a dramatically reduced quality of life for the affected individual, every effort has to be made to conduct these trials and possibly other ways for COPD detection have to be explored.

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