Is spirometry properly used to diagnose COPD? Results from the BOLD study in Salzburg, Austria: a population-based analytical study

*Bernd Lamprecht1, Andrea Mahringer1, Joan B Soriano2, Bernhard Kaiser1, A Sonia Buist3, Michael Studnicka1

1 Department of Pulmonary Medicine, Paracelsus Medical University Hospital, Salzburg, Austria
2 Program of Epidemiology and Clinical Research, Fundacio Caubet-CIMERA, Bunyola, Spain
3 Oregon Health and Science University, Portland, Oregon, USA

Received 10th July 2012; revised 24th November 2012; accepted 7th January 2013; online 28th March 2013

Abstract

Background: Current guidelines recommend spirometry to confirm a diagnosis of chronic obstructive pulmonary disease (COPD).

Aims: To investigate whether a self-reported diagnosis of COPD is associated with prior spirometry and whether a correct diagnosis of COPD is more likely when spirometry was performed.

Methods: We used data from the population-based Austrian Burden of Obstructive Lung Disease (BOLD) study. Participants were aged >40 years and completed post-bronchodilator spirometry. Reported COPD diagnosis and reported prior lung function test were based on questionnaire. Persistent airflow limitation was defined as post-bronchodilator forced expiratory volume in one second/forced vital capacity ratio <0.7, corresponding with COPD Global initiative for chronic Obstructive Lung Disease (GOLD) grade I+, and GOLD grade II+ was also investigated. A correct diagnosis of COPD was defined as a reported physician’s diagnosis of COPD and the presence of persistent airflow limitation.

Results: 68 (5.4%) of 1,258 participants reported a prior physician’s diagnosis of COPD. Of these, only 17 (25.0%) reported a lung function test within the past 12 months and 46 (67.6%) at any time in the past. The likelihood for a correct COPD GOLD grade I+ diagnosis was similar among subjects reporting a lung function test during the last 12 months (likelihood ratio 2.07, 95% CI 0.89 to 5.50) and those not reporting a lung function during the last 12 months (likelihood ratio 2.78, 95% CI 1.58 to 4.87). Similar likelihood ratios were seen when GOLD grade II+ was investigated and when lung function was reported at any time in the past.

Conclusions: One-third of subjects with a reported diagnosis of COPD never had a lung function test. When spirometry was reported, this did not increase the likelihood of a correct COPD diagnosis.

© 2013 Primary Care Respiratory Society UK. All rights reserved.

Keywords chronic obstructive pulmonary disease, spirometry

Introduction

Persistent airflow limitation is the physiological hallmark of chronic obstructive pulmonary disease (COPD). This can be confirmed by post-bronchodilator spirometry. A lung function test is recommended for subjects presenting with respiratory symptoms and/or exposure to tobacco smoke or other risk factors.1,2

In 2020 COPD will be the third leading cause of death worldwide. The increasing prevalence and mortality of COPD are related to both the ageing of the global population and the exposure to cigarette smoke or other harmful dusts and fumes.3 However, the epidemic of COPD is currently characterised by a high proportion of non-diagnosed cases.4 Underutilisation of spirometry, low test quality, and insufficient interpretation are likely to contribute to the underdiagnosis of COPD.5

We investigated whether subjects with a reported diagnosis of COPD would also report a lung function test in the past.
Theoretically, all subjects with reported COPD should have had such a test in the past if guideline recommendations are followed. However, a reported lung function test in the past does not necessarily guarantee that this test was performed and interpreted correctly. To estimate the overall performance of lung function tests, we analysed whether the likelihood for a correct COPD diagnosis was different in subjects reporting and not reporting a prior lung function test.

Methods

Study population
A gender-stratified random sample of 2,200 participants (1,100 men and 1,100 women) from the inhabitants of Salzburg County aged ≥40 years was examined in accordance with the Burden of Obstructive Lung Disease (BOLD) protocol. Details of the study population and the prevalence of airways obstruction have been reported elsewhere. The study was approved by the local ethical committee and all participants provided informed consent.

Study measures

Spirometry was performed according to American Thoracic Society (ATS) criteria by trained and certified technicians using the NDD Easy One™ spirometer (ndd Medical Technologies Inc, Switzerland) with participants in a seated position. Separate measurements were taken before and at least 15 mins after two puffs of salbutamol (200μg) from a metered dose inhaler, administered using a Volumatic spacer (GlaxoSmithKline, UK). Spirometry data were sent electronically to the Pulmonary Function Quality Control Centre in Salt Lake City, Utah, USA, where each spirogram was reviewed and graded using ATS guidelines.

Only spiromgrams that met ATS acceptability and reproducibility criteria were included – that is, at least three trials: two acceptable (free from artifact, sudden stops, and back extrapolated volumes >5.0% of forced vital capacity (FVC)) and reproducible (difference between the largest and second largest values <200mL) for both forced expiratory volume in one second (FEV1) and FVC.

Study technicians were continuously monitored. When a technician’s quality score dropped below a pre-set level, he/she had to stop testing and be re-trained and re-certified.

Questionnaire data

The BOLD questionnaires, administered by trained and certified staff, included information on respiratory symptoms, risk factors for COPD, health status, co-morbidities, respiratory diagnoses, and limitation of activity.

Definitions

In accordance with the Global initiative for chronic Obstructive Lung

Table 1. Demographic and clinical characteristics of participants (n=1,258)

|                        | Female (n=573) | Male (n=685) | Total (n=1,258) |
|------------------------|---------------|--------------|-----------------|
| Mean (SD) age in years |               |              |                 |
| 40–49                  | 168 (29.3%)   | 194 (28.3%)  | 362 (28.8%)     |
| 50–59                  | 170 (29.7%)   | 194 (28.3%)  | 364 (28.9%)     |
| 60–69                  | 153 (26.7%)   | 175 (25.6%)  | 328 (26.1%)     |
| 70–79                  | 52 (9.1%)     | 92 (13.4%)   | 144 (11.5%)     |
| ≥80                    | 30 (5.2%)     | 30 (4.4%)    | 60 (4.7%)       |
| Smoking status         |               |              |                 |
| Current smoker         | 123 (21.5%)   | 119 (17.4%)  | 242 (19.2%)     |
| Former smoker          | 130 (22.7%)   | 291 (42.5%)  | 421 (33.5%)     |
| Never smoker           | 320 (55.8%)   | 275 (40.1%)  | 595 (47.3%)     |
| Mean (SD) post-BD %pred FEV1 | 96 (17)    | 95 (17)      | 95 (17)         |
| Mean (SD) post-BD %pred FVC | 100 (16)  | 97 (15)      | 99 (15)         |
| Airways obstruction GOLD I+ | 130 (22.6%) | 174 (25.4%) | 304 (24.2%)    |
| Airways obstruction GOLD II+ | 52 (9.1%)   | 67 (9.8%)    | 119 (9.5%)      |
| No Airways obstruction | 443 (77.3%)  | 511 (74.6%)  | 954 (75.8%)     |
| Physician’s COPD diagnosis |           |              |                 |
| Yes                    | 31 (5.4%)     | 37 (5.4%)    | 68 (5.4%)       |
| No                     | 542 (94.5%)   | 648 (94.6%)  | 1,190 (94.6%)   |
| Lung function test (ever) |           |              |                 |
| Yes                    | 213 (37.2%)   | 305 (44.5%)  | 518 (41.2%)     |
| No                     | 360 (62.8%)   | 380 (55.5%)  | 740 (58.8%)     |
| Lung function test (12 months) |       |              |                 |
| Yes                    | 68 (11.9%)    | 85 (12.4%)   | 153 (12.2%)     |
| No                     | 505 (88.1%)   | 600 (87.6%)  | 1,105 (87.8%)   |

BD=bronchodilator, COPD=chronic obstructive pulmonary disease, FEV1=forced expiratory volume in one second, FVC=forced vital capacity.
Disease (GOLD) guidelines, persistent airflow limitation was defined as a post-bronchodilator FEV1/FVC ratio of <0.70, which corresponds to GOLD grade I and higher. We also report data for GOLD grade II or higher, which corresponds to FEV1/FVC ratio <0.70 and FEV1 <80% predicted. The Third National Health and Nutrition Examination Survey (NHANES III) reference equations were used to calculate predicted values. Doctor-diagnosed COPD was defined as a self-reported physician (general practitioners in Salzburg city and Salzburg county) diagnosis of COPD and/or emphysema. Among those who reported a diagnosis of COPD and/or emphysema, we also recorded how many reported a diagnosis of chronic bronchitis. Ever smoking (current or former smoking) was defined as smoking more than 20 packs of cigarettes in a lifetime or more than 1 cigarette/day for a year. A prior lung function test was defined as present when the question "Has a doctor or other health care provider ever had you blow into a machine or device in order to measure your lungs?" was answered with "yes". This was assessed for both the last 12 months and for any time in the past.

The staff who administered the questionnaire were trained and certified. In case of doubt they were able to explain the difference between a peak flow meter and a spirometer.

Statistical analysis
The statistical analysis was performed with SAS Version 9.1. Logistic regression (log-binomial regression model) analysis (unadjusted and adjusted) was used to investigate likelihood ratios associated with a correctly confirmed COPD diagnosis. Likelihood ratios were adjusted for age, sex, smoking, and reported respiratory symptoms. The level of significance is defined and described as p value, and p<0.05 was considered to be statistically significant.

Results
Of the 1,349 participants with complete questionnaire data and post-bronchodilator spirometry, 1,258 (93%) met the quality control criteria and were included in this analysis. The characteristics of this population are given in Table 1. The prevalence of persistent airflow limitation corresponding to COPD GOLD grade I+ and COPD GOLD grade II+ was 24.2% (304/1,258) and 9.5% (119/1,258), respectively. A prior physician’s diagnosis of COPD was reported by 5.4% of the study population in both males and females.

Prior physician’s COPD diagnosis and persistent airflow limitation
Only 11.5% (35/304) of subjects with persistent airflow limitation reported a prior physician’s diagnosis of COPD, while 88.5% (269/304) did not. On the other hand, 3.5% (33/954) of subjects without airways obstruction also reported a physician’s diagnosis of COPD. Therefore, 48.5% (33/68) of all reported COPD diagnoses were false positive and 88.5% of subjects with persistent airflow limitation were undiagnosed (Figure 1).

Prior lung function tests and reported diagnosis of COPD
The proportion of subjects who reported having a lung function test either in the last 12 months (Figure 2) or at any time in the past was 12.2% (153/1,258) and 41.2% (518/1,258), respectively. Among subjects with a reported physician’s diagnosis of COPD, only 25.0% (17/68) reported having a lung function test within the last 12 months and 67.6% (46/68) at any time in the past.

The likelihood ratio for a correct COPD diagnosis, defined as a reported prior physician’s COPD diagnosis and the concurrent presence of persistent airflow limitation (COPD GOLD grade I+), was 2.21 (95% CI 0.89 to 5.50) among those who reported having a lung function test during the last 12 months and 3.39 (95% CI 2.00 to 5.77) among those not reporting a lung function test during the same period (p=0.427 for comparison of the two likelihood ratios).

The corresponding likelihood ratios for a correct COPD diagnosis, defined as a reported prior physician’s COPD diagnosis (Figure 1).
and the concurrent presence of more stringent persistent airflow limitation (COPD GOLD grade II+) was 4.15 (95% CI 1.76 to 9.77) among those reporting having a lung function test during the last 12 months and 3.77 (95% CI 2.08 to 6.81) among those not reporting a prior lung function test during the same period (p=0.855 for comparison of the two likelihood ratios).

When a lung function test at any time in the past was evaluated, the likelihood ratio for a correctly confirmed COPD diagnosis (COPD GOLD grade I+) was 3.19 (95% CI 1.83 to 5.53) in those reporting a test and 2.63 (95% CI 1.15 to 6.05) in those not reporting such a test (p=0.707). For a more stringent spirometric definition of COPD (GOLD grade II+), the likelihood ratio for a correctly confirmed COPD
Spirometry – too little use to confirm COPD?

Underdiagnosis of COPD has been reported for many countries. For example, the rates of underdiagnosis in Spain and Sweden were reported to be 78% and 89%, respectively.12,13 Ten years after IBERPOC, underdiagnosis in Spain changed from 78% to 73%.12,13 Using data from the BOLD study, we recently reported a rate of underdiagnosis in Slovakia to be 89%, in comparison to 78% in Spain.12,13

Our findings show relevant shortcomings associated with the diagnosis of COPD and the use of spirometry. In the participants of the BOLD study in Salzburg, Austria we observed that: (1) among participants with a reported prior physician's diagnosis of COPD, only 25% reported a lung function test within the last 12 months and only 68% at any time in the past; (2) the likelihood of a correct COPD diagnosis was not different among those reporting or not reporting a prior lung function test; (3) our results suggest that lung function testing is greatly underused to diagnose and monitor COPD and, when used, the quality appears to be too low to establish a correct diagnosis.

Interpretation of findings in relation to previously published work

Underdiagnosis of COPD has been reported for many countries. For example, the rates of underdiagnosis in Spain and Sweden were reported to be 78% and 89%, respectively.12,13 Ten years after IBERPOC, underdiagnosis in Spain changed from 78% to 73%.12,13

On the other hand, our data show that many subjects with a reported diagnosis of COPD do not have persistent airflow limitation when spirometry is performed to internationally accepted quality control standards. These results indicate that a reported COPD diagnosis is poorly associated with airways obstruction on post-bronchodilator spirometry. On the one hand our data support the notion that many subjects with COPD are undiagnosed. On the other hand, a few others without obstructed airways (in our data 33/68 (48.5 %)) are wrongly misdiagnosed and costly and potentially harmful medication may be prescribed to them.15

In current clinical practice COPD is often diagnosed exclusively on the basis of the presence of respiratory symptoms,14 and some general practitioners still believe that spirometry is neither necessary nor helpful to diagnose COPD.17 This is in contrast to current guidelines (GOLD, National Institute for Health and Clinical Excellence, European Respiratory Society/American Thoracic Society) which state that a confident diagnosis of COPD can only be made with spirometry.18,19 Although spirometry does not fully capture the impact of COPD on a patient's health, it is still the gold standard for diagnosing the disease and monitoring its progression.20 To date, the BODE index (body mass index, airflow obstruction, dyspnoea, and exercise capacity) and other multicomponent indices used to assess the local and systemic consequences of COPD holistically include spirometry.20,21 Periodic spirometric measurements help to track a patient's decline in lung function, but useful information about lung function decline is unlikely from measurements performed more than once a year.2 In our sample, only 25% of those with a physician's diagnosis of COPD reported a lung function test within the last 12 months. Our data therefore indicate that spirometry is infrequently used for both diagnosing the disease and monitoring its progression.

The infrequent use of spirometry in GP offices and subsequent lack of experience causes uncertainty about both the performance and interpretation of a lung function test;22 as recently emphasised by the UK Primary Care Respiratory Society (PCRS-UK).23 A comparison of lung function test interpretations by family physicians and by pulmonary specialists showed concordant results in only 76% of cases.24 There are several explanations and reasons for the underuse of spirometry, of which time constraints, staffing, and poor training with subsequent lack of confidence in data interpretation are thought to be the most important contributors.25,26 The last of these might explain why spirometry (when performed) was not found to increase the likelihood of a correct respiratory diagnosis. However, well-trained office spirometry can be achieved and training of GP offices has been shown to increase the number of spirometry tests in the three months following training by about 60%, equivalent to an average (median) weekly increase in spirometry from one test every two weeks to one test every week.22

Implications for future research, policy and practice

The results of the BOLD study have shown that quality goals for spirometry tests can be met about 90% of the time in population-based samples of adults from several countries.27 Thus, more frequent use of properly performed lung function tests would be likely to increase the rate of correct COPD diagnoses and help to initiate early interventions (e.g. smoking cessation). This would result in improved patients' health status, slow down the decline in lung function,24 and could avoid exacerbations by prescribing appropriate medication.25,26 Centralisation of spirometry may be an alternative to well-trained office testing. A Community Respiratory Assessment Unit was established in 2004 in West London to provide high-quality spirometry and diagnostic support to primary care physicians. In this case, centralisation of spirometry via a dedicated service has been
shown to improve diagnosis and treatment of respiratory disease.11

Conclusions
We observed a significant underutilisation of spirometry among those with a diagnosis of COPD and, when spirometry was used, it was not found to increase the likelihood of a correct COPD diagnosis. These results should not be disregarded in the ongoing debate about screening for COPD, case finding, or selected early detection. However, to reduce underdiagnosis and overdiagnosis of COPD, every effort should be undertaken to establish quality managed spirometry programmes in primary care.

Handling editor Item Patel
Statistical review Gopal Netuveli

Acknowledgements
We acknowledge the support of the European Respiratory Society, Fellowship STRTF 326-2011.

Conflicts of interest
The authors declare that they have no conflicts of interest in relation to this article.

Contributorship
BL collected and analysed the data, drafted the manuscript and is the guarantor. AM analysed the data and helped to draft and revise the manuscript. BK analysed the data and was involved in drafting the manuscript. JBS, ASE, and MS helped to revise the manuscript.

Funding
The BOLD study in Salzburg, Austria was funded by unrestricted grants from the pharmaceutical industry, the local government of Salzburg, and the local public health insurance. BL is the recipient of a European Respiratory Society Fellowship (STRTF 326-2011). The sponsors had no role in the study design, data collection, data analysis, data interpretation, or writing the report.

References
1. Rabe KF, Hurd S, Anzueto A, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. GOLD Executive Summary. Am J Respir Crit Care Med 2007;176:532-55. http://dx.doi.org/10.1164/rccm.200703-4550X

2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management and prevention of COPD. 2011. Available from: http://www.goldcopd.org/.

3. Murray CJL, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 1997;349:1498-504. http://dx.doi.org/10.1016/S0140-6736(96)07492-2

4. Firle N, Lamprecht B, Schirnhofer L, Kaiser B, Studnicka M. Die Prävalenz der COPD. ASB, and MS helped to revise the manuscript. Respiration 2013;81(6):476-82. http://dx.doi.org/10.1159/000320251

5. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. BMJ 2007;334(7598):945-51. http://dx.doi.org/10.1136/bmj.39031936.04.001340

6. Celi R, Machee W, ATSERS Task Force. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23(6):932-46. http://dx.doi.org/10.1183/09031936.04.001340

7. Celi R, Cote CG, Marin JM, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity in chronic obstructive pulmonary disease. N Engl J Med 2004;350:1005-12. http://dx.doi.org/10.1056/NEJMoa0421322

8. American Thoracic Society. Statement: Standardization of spirometry, 1994 update. Am J Respir Crit Care Med 1990;142(3):812-17. http://dx.doi.org/10.1164/ajrccm.142.3.19900310

9. Starren ES, Roberts NJ, Tahir M, O'Byrne L, Haffenden R, Patel IS, Partridge MR. A comparison of national COPD prevalence with other populations. Eur Respir J 2009;34(2):168-92. http://dx.doi.org/10.1183/09031936.00138409

10. Miraftab F, Aslanian S, George D, Izban A. Interpreting COPD prevalence estimates: what is the true burden of disease? Chest 2003;123(5):1684-92. http://dx.doi.org/10.1378/chest.123.5.1684

11. Cambron G, Bettoncelli G, Tosatto R, et al. Underuse of spirometry by general practitioners for the diagnosis of COPD in Italy. Monaldi Arch Chest Dis 2005;65(3):1-6.

12. American Thoracic Society. Statement: Standardization of spirometry, 1994 update. Am J Respir Crit Care Med 1990;142(3):812-17. http://dx.doi.org/10.1164/ajrccm.142.3.19900310

13. Atkinson RJ, Wanner C, Goldman L, et al. The impact of smoking on health care resources in patients with COPD. Respir Med 2007;101(10):2476-82. http://dx.doi.org/10.1016/j.rmed.2007.12.008

14. Moore JL. Practice management and chronic obstructive pulmonary disease in primary care. Am J Med 2009;120(8):523-7. http://dx.doi.org/10.1016/j.amjmed.2007.04.009

15. Enright P, Vollmer WM, Lamprecht B, et al. Quality of spirometry tests performed by primary care physicians. Respir Care 2005;50(12):1639-48.

16. Levy ML, Quanjer PH, Hooker R, Cooper BG, Holmes S, Small J. General Practice Airways Group. Diagnostic spirometry in primary care: Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations: a General Practice Airways Group (GPIAG). Prim Care Respir J 2009;18:130-47. http://dx.doi.org/10.1016/j.pcrj.2009.09.0054

17. Yawn BP, Enright P, Lemanske RF, et al. Spirometry can be done in family physicians’ offices and alters clinical decisions in management of asthma and COPD. Chest 2007;132:1162-7. http://dx.doi.org/10.1378/chest.06-2722

18. Walters JA. Under-diagnosis of chronic obstructive pulmonary disease: a qualitative study in primary care. Respir Med 2008;102(5):738. http://dx.doi.org/10.1016/j.rmed.2007.12.008

19. Baan RA, McLean R, Straif K, et al. IARC working group on the evaluation of carcinogenic risks to humans: the carcinogenicity of paracetamol. Lancet 2003;362(9376):433-4. http://dx.doi.org/10.1016/S0140-6736(03)14112-5

20. Celli BR, Cote CG, Marin JM, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity in chronic obstructive pulmonary disease. N Engl J Med 2004;350:1005-12. http://dx.doi.org/10.1056/NEJMoa0421322

21. Etminan M, Huxley R, Patrick DL, et al. Smoking and COPD prevalence: a systematic review and meta-analysis. Chest 2007;131(4):960-6. http://dx.doi.org/10.1378/chest.06-3985

22. Lin K, Watkins B, Johnson T, Rodriguez JA, Barton MB. Screening for chronic obstructive pulmonary disease by primary care physicians. Am J Med 2007;120(8):523-7. http://dx.doi.org/10.1016/j.amjmed.2007.04.008

23. Enright P, Vollmer WM, Lamprecht B, et al. Quality of spirometry tests performed by primary care physicians. Respir Care 2005;50(12):1639-48.

24. Am J Respir Crit Care Med 1995;152:1107-36. http://dx.doi.org/10.1164/ajrccm.152.3.7663792

25. American Thoracic Society. Statement: Standardization of spirometry, 1994 update. Am J Respir Crit Care Med 1995;152:1107-36. http://dx.doi.org/10.1164/ajrccm.152.3.7663792

26. Hinkinson JL, Odenzanz JR, Fedan KB. Spirometric reference values from a sample of the general US population. Am J Respir Crit Care Med 1999;159:179-87. http://dx.doi.org/10.1164/ajrccm.159.1.9712108

27. Wirfält K, Ramström T, Olsson J. Spirometric reference values from a sample of the general US population. Am J Respir Crit Care Med 1999;159:179-87. http://dx.doi.org/10.1164/ajrccm.159.1.9712108

28. Peña VS, Miraftab F, Gabriel R, et al. Geographic variations in prevalence and underdiagnosis of COPD: results of the BERPOC multicentre epidemiological study. Chest 2000;118(4):981-9. http://dx.doi.org/10.1378/chest.118.4.981

29. Lindberg A, Jonsson AC, Rönnmark E, Lundgren R, Larson LG, Lundbäck B. Prevalence of chronic obstructive pulmonary disease according to BTS, ERS, GOLD and ATS criteria in relation to doctor’s diagnosis, symptoms, age, gender, and smoking habits. Respiration 2005;72:471-9. http://dx.doi.org/10.1159/000087670

30. Miraftab F, Aslanian S, George D, Izban A. Interpreting COPD prevalence estimates: what is the true burden of disease? Chest 2003;123(5):1684-92. http://dx.doi.org/10.1183/09031936.00138409

31. Starren ES, Roberts NJ, Tahir M, O’Byrne L, Haffenden R, Patel IS, Farahide MR. A centralised respiratory diagnostic service for primary care: a 4-year audit. Prim Care Respir J 2012;21(2):180-6. http://dx.doi.org/10.1016/j.pcrj.2012.00013

Available online at http://www.thepcrj.org