Quality of Spirometry in Primary Care for Case Finding of Airway Obstruction in Smokers

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Abstract
Background: Diagnosis of chronic obstructive pulmonary disease (COPD) and its severity determination is based on spirometry. The quality of spirometry is crucial. **Objectives:** Our aim was to assess the quality of spirometry performed using a spirometer with automated feedback and quality control in a general practice setting in Switzerland and to determine the prevalence of airflow limitation in smokers aged ≥40 years. **Method:** Current smokers ≥40 years of age were consecutively recruited for spirometry testing by general practitioners. General practitioners received spirometry training and were provided with an EasyOne™ spirometer. Spirometry tests were assigned a quality grade from A to D and F, based on the criteria of the National Lung Health Education Program. Only spirometry tests graded A–C (reproducible measurements) were included in the analysis of airflow limitation. **Results:** A total of 29,817 spirometries were analyzed. Quality grades A–D and F were assigned to 33.9, 7.1, 19.4, 27.8 and 11.8% of spirometries, respectively. 95% required ≤5 trials to achieve spirometries assigned grade A. The prevalence of mild, moderate, severe and very severe airway obstruction in individuals with spirometries graded A–C was 6, 15, 5 and 1%, respectively. **Conclusion:** Spirometries in general practice are of acceptable quality with reproducible spirometry in 60% of measurements. Airway obstruction was found in 27% of current smokers aged ≥40 years. Office spirometry provides a simple and quick means of detecting airflow limitation, allowing earlier diagnosis and intervention in many patients with early COPD.

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Introduction

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide [1] and is predicted to be the third leading cause of death worldwide by 2020 [2]. Smoking is the leading cause of

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COPD and there is good evidence that smoking cessation may influence the progression of COPD [3–5]. However, evidence suggests that awareness of COPD in potential sufferers is insufficient to impact on smoking behavior [6]. Screening for airflow limitation in smokers, therefore, may be beneficial, in particular in those attempting to quit smoking [7, 8]. Recent studies indicate that smokers attending smoking cessation counseling programs with spirometrically identified airway obstruction have slightly higher cessation rates compared with those with a normal spirometry [9, 10]. These differences in quit rates become more pronounced in subgroups of smokers with moderate or severe airway obstruction [9, 10].

In primary care, COPD is under- and misdiagnosed [11] and a questionnaire-based medical history is inferior to spirometry for the identification of patients with COPD [12]. Based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines [13], COPD is defined as airway obstruction that is not fully reversible, and thus spirometry is needed to identify COPD. In one study of office-based spirometry, over 30% of patients diagnosed with COPD in primary care were found to have normal spirometries, when tested in a pulmonary function laboratory [11]. Spirometry is technically demanding and also, depending on the devices chosen, calibration prior to the tests is needed. Further, the test is dependent on the patients' cooperation [14]. In a study to assess the impact of training during a spirometry workshop, only 33.1% of spirometries performed by trained primary care providers and 12.5% performed by control group participants achieved the requirement of at least 2 acceptable spirometry maneuvers that were in accordance with quality criteria as defined by the American Thoracic Society (ATS) [15]. However, this may be more symptomatic of spirometry in general rather than indicative of the quality of technicians in primary care. Schermer et al. [16] reported a small but statistically significant difference in lung function values between spirometry performed in general practice and in a pulmonary function laboratory. In terms of reproducibility, though, the quality of spirometry did not differ significantly between the 2 settings.

In recent years, new devices with automated feedback mechanisms and quality control measurement to simplify the procedure for the investigator have become available for use in primary care. The quality control and feedback algorithms in such devices have been standardized in a consensus statement from the National Lung Health Education Program (NLHEP) [17].

We conducted a study to evaluate the quality of spirometric measurements by spirometers with automated feedback and quality control in primary care in Switzerland. Further, we wanted to determine the prevalence of airflow limitation in smoking patients aged ≥40 years consulting general practices.

Methods

A total of 440 out of 1,800 general practitioners (GPs) taken from a Swiss physicians' register (maintained by the Swiss Medical Association, FMH) agreed to participate in the study in response to a one-off bulk mailing of invitation letters. No specific recruitment criteria for participating GPs were used. The Easy-One™ spirometer (ndd Medizintechnik AG, Zurich, Switzerland) with disposable mouthpieces was provided without charge to the participating physicians. Before commencing the study, participating physicians and their practice nurses were instructed on how to perform spirometry according to ATS guidelines by representatives of the spirometry sales company [18]. This instruction took place at the physician's office and took approximately 1–2 h. They were taught how to operate the spirometer and how to perform the spirometry test. In addition to theoretical instruction, all participants were examined on their practical ability according to ATS guidelines [18]. Physicians were asked to recruit at least 60 current smokers aged ≥40 years, independently of the reason for consultation. For simplicity, inclusion was limited to current smokers only. There were no data collected on previous spirometries or confirmed diagnoses. The study was approved by the institutional Ethics Committee.

In this study, we used a spirometer with ultrasonic transit-time flow measurement technology with built-in software for quality control and feedback for the examiner. The EasyOne spirometer is factory calibrated and, due to its operating principle, does not need further calibration [19]. All spirometry measurements were performed in a seated position and required the use of a nose clip. The quality of spirometry was assessed automatically by the spirometer, as suggested in the consensus statement from the NLHEP [17], using the grading recommended from that report. The spirometry data were classified in quality control (QC) grades A–D and F (table 1). A mean QC grade was assigned to spirometry data using the criteria of Ferguson et al. [17].

The built-in feedback mode gives instructions that are displayed on the screen of the device as follows:
- 'don't hesitate': back-extrapolated volume >150 ml or >5%, whichever is greater
- 'blast out faster': time until peak flow >120 ms
- 'blow out longer': expiration time <2 s or volume during last 0.5 s >100 ml when expiration time is <6 s
- 'good effort, do next': test meets the above-mentioned criteria
- 'blast out harder': peak flow not reproducible; difference with respect to best test >1.0 liters/s
- 'deeper breath': forced expiratory volume in 1 s (FEV_1) or forced vital capacity (FVC) not reproducible; difference with respect to best test >150 ml
- 'test complete': 3 acceptable tests, FEV_1 and FVC within 200/250 ml (after 5 trials)

For the assessment of the prevalence of airway obstructions in smoking patients, we considered only spirometries with quality grades A–C. Quality grades A–C ask for a reproducibility of at

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Fig. 1. Mean QC grades of spirometry measurements according to the number of spirometries performed by each GP (n = 29,817).
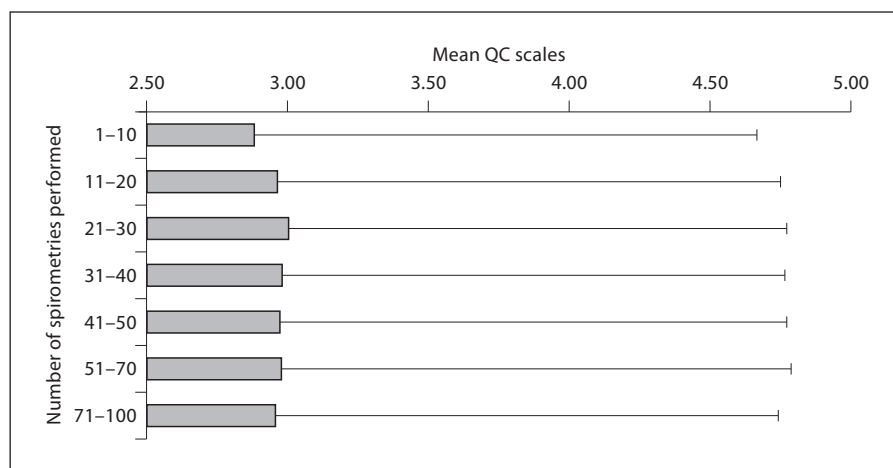
least 250 ml. For the predicted values, we used the reference values by Brandli et al. [20] (Swiss study on Air Pollution and Lung Diseases in Adults). Interpretation of the spirometry data was performed by the authors according to the criteria of the GOLD committee, Hardie et al. and Fabbri et al. [1, 21, 22], with the exception that prebronchodilator data was used. Therefore, airway obstruction was defined as having a prebronchodilator $FEV_1/FVC < 70\%$ in patients younger than 70 years of age, $FEV_1/FVC < 65\%$ in patients between 70 and 80 years of age and $<60\%$ in patients older than 80 years of age. Possible restriction was assigned if $FEV_1/FVC >$ lower limit of normal (LLN), FVC < LLN and $FEV_1 <$ LLN.

Statistical Analyses

Continuous variables are expressed as means (with standard deviations in parentheses), and categorical variables are expressed as relative frequencies and percentages. Analysis was performed with use of SPSS version 12 and Microsoft® Excel 2003 software.

Results

Patients

A total number of 440 GPs participated in this study. The mean number of spirometry tests done by each GP was 67. In total, 30,991 tests were performed. After deleting repeated tests in the same patient (the spirometries with the lower quality grades were deleted), 29,817 tests were available for analysis of the quality of the spirometry.

Quality of Spirometry

Of the spirometry tests included in the analysis, the distribution according to the quality grades was as follows: grade A, 10,104 (33.9%); grade B, 2,115 (7.1%); grade C, 5,778 (19.4%); grade D, 8,295 (27.8%); grade F, 3,525 (11.8%).

Table 1. Criteria for QC grading of spirometry measurements [17]

QC grade	Criteria
A	At least 3 acceptable tests AND the difference between the best 2 FEV_1 and FVC values is ≤150 ml
B	At least 3 acceptable tests AND the difference between the best 2 FEV_1 and FVC values is ≤200 ml
C	At least 2 acceptable tests AND the difference between the best 2 FEV_1 and FVC values is ≤250 ml
D	At least 2 acceptable trials but the results are not reproducible Quality message: 'result not reproducible' OR only one acceptable trial Quality message: 'only one acceptable trial'
F	No acceptable test available

The quality of spirometric data was influenced by total number of tests performed (fig. 1). GPs who performed fewer than 10 tests had the lowest mean quality scores. The mean QC grade increased notably in GPs with more than 10 tests and was highest in GPs with 21–30 tests. Quality did not continue to improve in GPs with >30 tests and was actually lower in GPs with 71–100 tests compared with GPs with 11–70 tests. Overall, 95% of the subjects with QC grade A achieved the results with less than 5 trials (fig. 2).
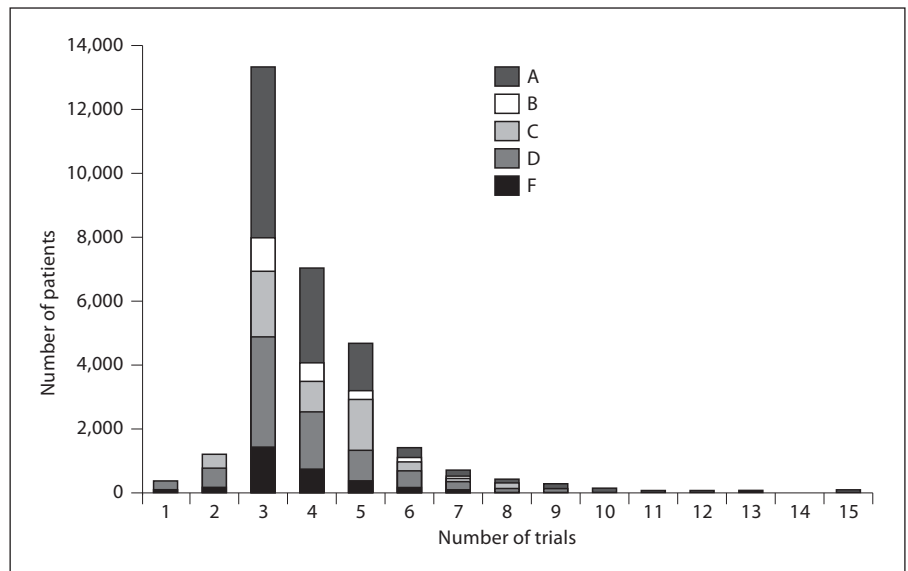
Fig. 2. Number of trials needed to achieve a certain quality grade (n = 29,817).

Table 2. Diagnosis of airflow obstruction in smokers aged ≥40 when applying the reference values by Brandli et al. [20]

	Measurements	Acceptable tests, %
Total measurements	24,995	
Unclassified	9,911	
Quality grade A–C	15,084	100
Normal spirometry	8,533	57
Mild obstruction	951	6
Moderate obstruction	2,217	15
Severe obstruction	818	5
Very severe obstruction	245	2
Possible restriction	2,320	15

Unclassified: Quality grades D and F.

Prevalence of Airflow Limitation

A total of 4,822 spirometries from subjects younger than 40 years of age were deleted for the analysis of airflow limitation; thus, the sample consisted of 24,995 spirometries in smokers aged 40 and above. Their mean age was 51.6 years; 58.6% were male and 41.4% were female. Using the reference values from Brandli et al. [20] airway obstruction was found in 27% of patients (table 2). Mild (6%) and moderate (15%) airflow obstruction were collectively more commonly detected than severe (5%) and very severe (1%) airflow obstruction. Possible airflow restriction was detected in 15% of the study population (table 2).

Discussion

The present study evaluated the quality of spirometry data obtained in a general practice setting using a hand-held spirometer equipped with automated feedback and QC. We found that in excess of 60% of spirometry tests performed were acceptable in terms of quality. From these data, we determined that the prevalence of airflow limitation in Swiss smokers aged ≥40 years is 27%.

The consensus statement from the NLHEP recommends that office spirometry should be performed in all patients ≥45 years, patients presenting with respiratory symptoms and patients desiring a health assessment [17]. Such a recommendation is dependent on spirometry performed in general practice being of sufficient quality to allow the accurate diagnosis, treatment and monitoring of patients with COPD. The current study demonstrates that good-quality spirometry is achievable using a spirometer equipped with automated feedback and QC. More than half of the spirometry tests included in our analysis were assigned a quality grade A–C.

The key strengths of our study are the large number of patients (especially considering the estimated 7.6 million population of Switzerland), the general practice setting and the standardized use of the same type of spirometer. Compromises were necessary, however, and notable weaknesses include consecutive, nonrandomized data collection, nonrandomized selection of GPs, absence of a comparator group as well as absence of data on pre-existing, known airway obstruction and other diseases. Since

completing this study, the criteria for quality grades have been revised [23].

Our results indicate the existence of a training effect in that the lowest mean quality grade was assigned to GPs who had performed fewer than 10 tests. The mean quality increased with the number of tests performed, reaching a peak in GPs who had performed 21–30 tests. Thereafter, the mean quality was lower, suggesting that both initial training and refresher training may be important in maintaining high standards of spirometry. The benefit of refresher training is illustrated by the results of the Burden of Obstructive Lung Disease study [24]. In this study, which also used the EasyOne spirometer, only 4% of patients were excluded from the analysis due to unusable spirometry data. The quality of spirometry was continuously monitored and, if quality levels dropped below a certain predefined threshold, the technician performing spirometry was required to be retrained and recertified before continuing. The lack of correlation between experience and quality, over and above the initial training effect observed in the current study, reaffirms the suggestion that refresher training is central to maintaining high standards of spirometry. Although poor spirometry is often attributed to error or lack of coaching on the part of the investigator, good spirometry also requires a degree of cooperation and effort from the patient. This study did not investigate what proportion of poor-quality spirometry was due to a lack of cooperation from the patient.

The NLHEP consensus statement also stipulates that the automated feedback and QC mechanisms of spirometers, such as the one used in this study, should permit >90% of patients to meet the required QC threshold in fewer than 5 trials. The results of this study suggest that this stipulation was not achieved. Nevertheless, the quality of the spirometry performed here is higher than in a previous study [15]. In a prospective, randomized controlled trial, fully acceptable and reproducible tests were only achieved in 13.5% of patient tests in the trained GP group and in 3.4% of the control GP group [15]. In our primary care environment, 95, 91 and 87% of tests graded A, B and C, respectively, were achieved in 5 or fewer trials, suggesting that the use of the EasyOne spirometer came close to achieving the stipulated >90% success rate.

The prevalence of airflow limitation in our population of Swiss smokers aged ≥40 years was 27%. A mild to moderate airway obstruction was found in 21% and a severe to very severe airway obstruction in 6%. The prevalence of airflow limitation observed in this study concurs with that reported in similar studies. Zieliński et al. [8] observed airflow limitation in 41% of Polish smokers aged ≥40 years and van Schayck et al. [7] reported that 18% of Dutch smokers aged 35–70 years had an FEV_1 of <80% predicted.

The use of spirometry in general practice is not universally supported due to the risk of misdiagnosis and the risk that smoking behavior may be reinforced in those smokers found to have normal lung during spirometry testing [25]. However, taking into account that recent published trials suggest that early intervention may modify the clinical course of the disease [26, 27], early detection of COPD could be important.

The cost of spirometers remains one of the most significant barriers to the widespread use of spirometry in primary care. However, it is probable that office spirometers will not be prohibitively expensive in the future and that spirometry in general practice will become more commonplace. The price of office spirometers has decreased in recent years, and this trend is likely to continue.

In summary, spirometric screening for patients with a high risk for COPD in general practice using a spirometer with automated feedback frequently fulfills the criteria of spirometry in a pulmonary function laboratory. Furthermore, office spirometry provides a simple and quick means of detecting airflow limitation. Though this would need to be confirmed in a specialist laboratory, screening in this way would allow earlier diagnosis and intervention in many patients with early COPD.

Acknowledgments

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