DISCUSSION PAPER

The use and abuse of office spirometry

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Summary

Spirometry programs (outside of primary care settings) designed to detect COPD in the general adult population are not justified, since the true positive yield (airway obstruction with an FEV₁ below 60% predicted) is very low, and the false positive rate is very high. However, spirometry is greatly under-utilised by GPs who often prescribe inhalers for patients haphazardly. Inhalers for COPD are expensive and risk serious side-effects, so they should not be prescribed for current or former smokers without confirming severe airway obstruction. A large program in Finland has shown that some GPs can perform good quality spirometry. If good quality spirometry is not available in the GP's office, patients should be referred to a local resource for pre- and post-bronchodilator spirometry. More studies are needed to show that GPs use spirometry results systematically to make decisions which truly benefit their patients with asthma or COPD.

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P Enright. *Prim Care Resp J* 2008; **17**(4): 238-242. doi:10.3132/pcrj.2008.00065 **Keywords** spirometry, case-finding, screening, reliability, primary care, COPD, asthma, FEV₁/FVC

General Pr See papers by Tuomisto et al (page 226) and Rytila et al (page 232)

Introduction

rodi In this issue of the PCRJ, two papers from Finland describe the surprising success of programs to promote the widespread use of spirometry in the offices (consulting rooms) of primary care practitioners.^{1,2} Similar efforts in other countries have not been successful, despite local pulmonary specialists providing free training, and drug companies providing free spirometers and supplies.³⁻⁷ The three most common evidence-based indications for office spirometry are: to detect COPD; to determine the severity of asthma; and to measure the response to asthma medications.

Screening spirometry is a waste of resources

For more than 30 years, pulmonary specialists have been trying to get primary care practitioners to "Detect COPD *Early*," but we still don't have the evidence that these efforts help more patients than they hurt. Public campaigns in the United States (USA) tell smokers to "Test Your Lungs; Know Your Numbers." Instead, I think that patients should be told to "Blow Hard (into a spirometer) Before You Suck Deeply"

r 3ct (from an expensive inhaler). GPs should not even consider prescribing an inhaler for COPD until severe airway obstruction has been confirmed by spirometry.

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Hundreds of thousands of smokers have received spirometry testing in national campaigns which have produced tens of thousands of "cases" of COPD. However, according to extensive literature reviews, the Agency for Healthcare Research and Quality (AHRQ) group in the USA has concluded that such programs are not justified.^{8,9} In fact, spirometry done in medical care settings for patients with chronic respiratory symptoms (at high risk for lung disease) is true "case finding", whereas "screening" spirometry is done outside of a physician's office or hospital, often for anyone who is interested in the test (and thus at low risk for lung disease).^{10,11} Screening spirometry projects are often said to be done to "increase awareness" of COPD, but considerable harm can occur when the person is inappropriately told that the results are abnormal.^{12,13} Misclassification of spirometry results commonly occurs due to poor coaching, poor inspiratory or expiratory effort, an inaccurate spirometer, or inappropriate interpretation of the spirometry tracing.

Smokers are not more likely to guit smoking successfully when faced with abnormal spirometry results.^{14,15} All smokers, regardless of spirometry results, should be helped by primary

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care practitioners to quit smoking – and this help should include the prescription of bupropion or varenicline for those who have failed less expensive interventions.¹⁶ So, prompting smoking cessation is not a valid rationale for promoting screening spirometry; you should not need a "stage prop" (abnormal test result) to convince a smoker to allow you to help him or her quit smoking permanently.

False positive rates for "mild COPD" are very high

Somehow, COPD guidelines published by pulmonary specialists during the past decade became biased towards increasing prescriptions for expensive inhalers. Patients with a normal forced expiratory volume in one second (FEV1) were classified as having mild COPD (GOLD Stage 1) if their FEV₁/forced vital capacity (FVC) ratio was below 0.70.^{17,18} But the FEV1/FVC ratio decreases with age in healthy neversmokers, so the false positive rate for airway obstruction (and thus COPD) - as defined by several pulmonary professional societies - increases above the age of 50 and is very high in patients aged 70 years or above.¹⁹⁻²¹ The fifth percentile from spirometry reference equations derived from a healthy population sample should be used to determine the lower limit of the normal range (LLN) for both the FEV₁/FVC ratio and for the FEV1 itself.22 The age and gender-corrected LLNs are calculated automatically by the majority of commercially available spirometers, so there is no need to use the faulty. 0.70 ratio in practice.

There is also no need to detect COPD "early" because there is no evidence that GOLD Stage 1 is a disease or a risk factor.^{23,24} The risk of a subsequent rapid decline in lung function in an adult smoker with airway obstruction is substantially increased only after their FEV₁ has fallen to below about 65% predicted.²⁵

About one-third of adult smokers with airway obstruction found during screening spirometry will not have airway obstruction ten minutes after inhaling a fast-acting bronchodilator.²⁶ By definition, COPD is then ruled out. This finding increases the probability of asthma in those with asthma-like symptoms. Up to a half of adults with asthma are current smokers in some countries,^{27,28} and their asthma will be more easily controlled if they successfully quit smoking.²⁹ Primary care practitioners (outside of Finland) rarely have the time to repeat spirometry after salbutamol inhalation, so it follows that they should not make a diagnosis of COPD in a patient with mild to moderate airway obstruction without referring these patients for post-bronchodilator spirometry.³⁰ Differentiating asthma from COPD is important because asthma infrequently responds to the anti-cholinergic inhalers often prescribed for COPD, and the prognosis for asthma is much better.

Mild restriction is not early COPD

"Mild restriction" is a non-specific, non-diagnostic, spirometry result. It is often due to poor inspiratory or expiratory effort, not measuring the patient's height properly (men often exaggerate their height when asked), use of inappropriate reference values (e.g. using Caucasian reference values when testing a black patient), or using an interpretation scheme which is not evidence-based. A low FVC without a low FEV₁/FVC ratio is often interpreted as restriction, but at least half of such patients have normal lung volumes when referred to a pulmonary function laboratory and tested in a body plethysmograph.³¹ Clinical research is needed to determine the clinical correlates of this non-specific spirometry pattern, much of which is probably due to obesity or poor effort. There is no evidence that mild "spirometric restriction" is due to "air trapping" secondary to "small airways disease" or early COPD in patients who would benefit from treatment with inhalers.¹³ I would not use spirometric "restriction" for medical decision-making, or as an indication for referring the patient for complete pulmonary function testing, unless the FVC is repeatably below 60% predicted, or the patient has an abnormal chest x-ray, or has dyspnoea on exertion, but is not obese.

In order to minimise misclassification of spirometry interpretations, we should learn to accept uncertainty when the results are near the LLN (borderline abnormal), the quality of the test was poor (due to sub-maximal efforts), and when post-bronchodilator results are unavailable.¹¹

Yet spirometry is greatly under-utilised

According to studies in the USA, the majority of people reporting a doctor-diagnosis of COPD have never had spirometry testing to confirm the diagnosis.^{4,32} There was a wide geographic variation in the use of spirometry to confirm COPD,³³ and this is probably true between and within many other countries. This practice is akin to prescribing antihypertensive medications without measuring blood pressure... While they may be smokers with a chronic cough and perhaps some dyspnoea due to poor conditioning, many of these patients do not have airway obstruction.³⁴

Should GPs buy a spirometer or simply order spirometry tests?

In most countries, a minority of primary care practitioners have purchased a spirometer, and few have actually used it during the past month.^{3,5,35,36} Some GPs use a spirometer several times a month, but many of the tests fail the standard goals for good quality.³⁷ In the USA, a nurse or technologist performs the spirometry tests (not the doctor), but the majority of these staff have not been trained to perform spirometry tests properly, and post-bronchodilator spirometry is almost never done due to time constraints.³⁸

A few GPs purchase a spirometer and use it for the majority of their patients who have an indication for spirometry – smokers over age 40 with dyspnoea, or patients with poorly controlled asthma. These "early adopters" report that the spirometry results often assist medical decisionmaking.³⁹⁻⁴¹ However, the majority of GPs who are given a spirometer and receive training no longer use spirometry after the first few months.6

For most GPs in urban and suburban settings, the best solution may be for a third-party expert to perform the necessary spirometry tests.⁴²⁻⁴⁵ In the USA, about half of the spirometry tests done around the time of the initial diagnosis of COPD are done in a traditional pulmonary function laboratory,⁴ but this approach is greatly under-utilised, perhaps due to long delays, inconvenience, or excessive cost. Regularly-scheduled "free clinics" in convenient locations (such as neighbourhood pharmacies or community centres) have successfully been used in Poland.⁴⁶ Another approach, which has proved to be successful in some locations, is for an itinerant nurse or certified technologist to schedule monthly visits to the GP's office to test patients who have an indication for spirometry.^{7,43} More than 80% of the tests done by

important COPD

As described by Rytila et al and others,47 lower false positive rates will be obtained - with no loss of sensitivity for smokers who may benefit from a COPD inhaler - if inexpensive pocket spirometers are used to exclude substantial airway obstruction in primary care settings. Furthermore, inexpensive mechanical peak expiratory flow (PEF) meters can be used; a ground-breaking report from the PLATINO and BOLD studies demonstrates that a normal PEF measurement can confidently exclude GOLD Stage III or more severe COPD in smoking adults.⁴⁸ This stepped approach is efficient because only the fraction of patients with a low PEF or an FEV1 below 60% predicted need a referral to a specialty service for good guality pre- and post-bronchodilator spirometry to confirm postbronchodilator airway obstruction.

Drugs for COPD?

The inhalers prescribed for COPD are very expensive and risk serious side-effects, including death by arrhythmia,49-53 and thus should not be considered unless an FEV1 below 50% predicted has been confirmed by good quality spirometry testing.[®] The effectiveness of COPD inhalers has not been weighed against the costs and risks of these drugs.⁵⁴ There is an imbalance of information in the promotion of these inhalers. More than 5 billion Euros worth of inhalers are currently sold worldwide each year, providing an irresistible financial imperative for drug companies to expand this market. Industry-sponsored clinical trials are likely to be biased by their inclusion/exclusion criteria, comparators, choice of outcome measures, analysis details, and conclusions.

I worry that many smokers who are prescribed an inhaler for COPD feel that they don't need to try to stop smoking. About half of the participants in large COPD clinical trials remain current smokers throughout the study.55,56 In my opinion, efforts by health care professionals to promote inhaler compliance in such patients should be re-directed to help them to guit smoking.

Spirometry for patients with asthma

Tuomisto and coworkers from Finland report in this issue that good guality flow-volume curves were obtained about 80% of the time by primary care doctors who referred patients with asthma to a pulmonary specialist.¹ This very high success rate in meeting ATS goals for good quality spirometry is much better than previously reported in other primary care settings.^{42,56,57} However, success in meeting the ATS goal of 5% repeatability of FEV₁ was not measured by this study,¹ yet A normal peak flow rules out clinically FEVD increase of 10% is often a clinically

> Normal spirometry does not rule out asthma in a patient with a history of asthma-like symptoms or in a patient taking asthma controller medications;⁵⁸ however, spirometry is often useful for excluding the possibility of COPD in adult smokers with asthma-like symptoms (as discussed above).¹¹ Spirometry (i.e. a low FEV₁) will sometimes reveal that asthma is more poorly controlled than suggested by the frequency of symptoms and use of a rescue inhaler reported by the patient.59 A low FEV1 is also a strong predictor of a subsequent asthma exacerbation.^{60,61} FEV₁ can be measured accurately even during acute asthma attacks62 and helps to determine the need for hospitalisation. The ability of primary care physicians to utilise the FEV₁ to make better clinical decisions and improve clinical outcomes in patients with asthma (when compared to reliance on the clinical history and peak expiratory flow) remains to be studied.

Conclusion

In summary, some general practitioners can successfully use office spirometry to detect severe COPD and asthma which is less well controlled than indicated by symptoms; however, many other GPs should refer patients with respiratory symptoms to a local service which can provide good quality pre- and post-bronchodilator spirometry and interpretations.

Conflict of interest declaration

During the past three years, the author has received payments for consulting on spirometry quality assurance programs for phase III clinical trials from Pfizer (varenicline for smoking cessation in patients with COPD) and InterMune (for patients with idiopathic pulmonary fibrosis). He has received no consulting or travel expense reimbursement from any companies which make pulmonary function equipment or spirometers.

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