Documentation of Airflow Obstruction Is Essential to Confirm the Diagnosis of COPD: Are Handheld Spirometers in an Office Setting Valid?

Chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the United States, is estimated to affect over 24 million Americans. Despite recent efforts by many to raise public and medical-community awareness of COPD, appropriate efforts to detect COPD earlier are still inadequate. To a lesser degree, this is also true for another prevalent obstructive airway disease: asthma. Currently the accepted standard for documenting airflow obstruction is spirometry. If spirometry is appropriately used to test individuals at risk for COPD (case-finding), as recommended by clinical practice guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD),[1] the American Thoracic Society/European Respiratory Society,[2] and the National Lung Health Education Program,[3] spirometry can be very efficient in determining the presence or absence of airflow obstruction, often well before the patient reports early signs/symptoms of COPD (chronic cough, with or without sputum production, dyspnea on mild exertion, or wheeze)[3] or substantial decrements in their activities of daily living.

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The medical community, from primary care to sub-specialists, has historically not hesitated to rapidly adopt tests (eg, blood pressure, cholesterol, bone density, mammography, fasting blood sugar, hemoglobin A1C) as part of routine practice. Consensus (common sense) usually prevails early on, before there is proof of patient impact, and these tests are routinely used, based on the rationale that the tests can identify the diseases earlier in patients at risk. In some cases their use has been appropriately questioned retrospectively, when more evidence became available. The debate on whether spirometry should be used in the office setting continues to rage, yet the diagnosis of COPD continues to be made without spirometry confirmation of airflow obstruction. This can lead to misdiagnosis and administration of unneeded therapies, or to under-diagnosis and a lack of optimal therapy. On a positive note, the use of spirometry among clinicians has markedly increased in the past few years, but the glass is half full, because spirometry remains underused.

Spirometers used in the office setting should certainly be cleared by the Food and Drug Administration and certified by the American Thoracic Society, and probably should meet the criteria for an office spirometer outlined in the National Lung Health Education Program's spirom-etry review process.[4] It is crucial that office spirometers are accurate and yield reproducible results similar to laboratory spirometers, but office spirometers must also be easy to use and interpretable by the office staff and clinicians. Such a handheld spirometer (EasyOne, ndd Medical Technologies, Chelmsford, Massachusetts) is studied in the article by Barr et al in this issue of RESPIRATORY CARE.[5] Barr et al compare readings from the EasyOne (an ultrasonic flow-sensing spirometer) to those from a volume-sensing dry rolling seal laboratory spirometer.

Barr et al initially conducted spirometry with 12 individuals who had extensive experience with spirometry testing, and then with 24 subjects unfamiliar with spirometry testing, none of whom had poorly controlled lung disease. The study was well controlled and used appropriate statistical comparisons, including analysis of the limits of agreement between the 2 spirometers. A limitation of the study is that Barr et al did not test patients with different degrees of airflow obstruction. Though the EasyOne gave lower values than the laboratory spirometer for all measurements except peak flow (forced expiratory volume in the first second [FEV_1] and forced vital capacity [FVC]), Barr et al found that the results were generally reproducible and valid. Specifically, in the clinical testing with the 24 spirometry-naïve subjects, the EasyOne met the criteria for reproducibility of FEV_1, narrowly missed the reproducibility criteria for FVC, met the validity criteria for FVC, and came very close to meeting the validity criteria for the FEV_1. Barr et al attribute the latter results to a training effect. These results support those of other studies of the EasyOne.[6–8] In summary, the findings from Barr et al[5] further substantiate that the EasyOne is justified for use in clinical, research, and occupational settings.

Certainly, more sophisticated genomic/proteomic/biochemical markers will be developed to detect COPD and other airway diseases earlier in their course and/or to follow the efficacy of medical interventions. But those tests are either not yet developed or not ready for routine clinical use. The purpose of the study by Barr et al[5] was not to debate what, if any, medical intervention should be chosen after an earlier diagnosis of airflow obstruction is made—that is, to treat or not to treat—but rather only to validate a user-friendly

tool that can be routinely used in the clinic to make an earlier diagnosis of airflow obstruction. Further trials should be conducted with patients identified in the early stages of COPD to study the early pathogenesis of this disease and to determine if interventions change the course of the disease. Additional well controlled studies should also be done to confirm the reproducibility and validity of additional spirometers for earlier diagnosis in the office setting, to determine if the results from such testing impact diagnosis and management in the primary care and sub-specialty settings, and if these actions improve outcomes and prognosis for our patients.

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