Abandoning FEV₁/FVC < 0.70 to Detect Airway Obstruction

An Essential Debate but With the Right Emphasis?

To the Editor:

In recent Point/Counterpoint Editorials in CHEST (November 2010), Drs Celli and Halbert¹ argue in favor of and Drs Enright and Brusasco² argue against using the fixed cutpoint for FEV₁/FVC < 0.70 to define airflow obstruction when diagnosing COPD. This is clearly an important debate, but we believe that the authors fail to address some essential points in their respective contributions.

They base their arguments mainly on issues related to other conditions (ie, hypertension), detection of obstruction in the general population, comparison of prevalence figures between countries, underdiagnosis of COPD, and population-level evidence regarding FEV₁/FVC decline with age.³ However, in our view, the debate about the preference for the 0.70 or an age- and sex-specific FEV₁/FVC cutpoint should focus on the consequences of this choice when diagnosing individuals.

Primary care physicians (PCPs) are often the first health-care professionals that people will turn to when they experience respiratory symptoms. Thus, in many cases it will be the PCP who needs to decide whether the symptoms are caused by COPD or by one of the many other causes for the patient’s symptoms.⁴ Availability of spirometry is indeed increasing in many countries, and PCPs will often need to interpret the spirometry results, even though they are not respiratory experts. By stating that “it is the evaluating physician who ultimately decides the medical significance of an abnormal value in a specific patient encounter,” Drs Celli and Halbert⁵ do seem to recognize this, but at the same time they cast doubt on PCPs’ ability to judge the significance of an abnormal value for the FEV₁/FVC (“It can be easily understood by clinicians, lowering some of the barriers to spirometry.”).

The best thing we can do to support PCPs in deciding whether an FEV₁/FVC value is medically significant in a particular patient is to provide them with cutpoints that leave no indefiniteness about the role age, sex, and race have in the interpretation of the patient’s spirometry test. We have recently shown that using lower limit of normal (LLN) cutpoints instead of FEV₁/FVC < 0.70 substantially reduces the number of false-positive interpretations in primary care, especially in elderly subjects (Fig 1).⁶ We agree with Drs Enright and Brusasco⁷ that switching to LLN cutpoints does not need to be that complicated, as most electronic spirometers already incorporate LLN equations, and even if they do not, a simple table or graphical aid—which is no more difficult to read than growth charts for children—could solve this.

From a research point of view, the million-dollar question is whether a middle-aged or elderly subject who has an LLN < FEV₁/FVC < 0.70 when being evaluated for possible COPD actually shows abnormal progression of airflow obstruction or other clinical features that justify a COPD diagnosis. Currently, there is insufficient evidence to answer this question. We are very interested to learn the responses of the authors on these points.

Bas Robberts, MD
Tjard Schermer, PhD
Nijmegen, The Netherlands

Affiliations: From the Department of Primary and Community Care, Radboud University Nijmegen Medical Centre.

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Correspondence to: Tjard Schermer, PhD, Radboud University Nijmegen Medical Centre, Department of Primary and Community Care (117-ELG), PO Box 9101, 6500 HB Nijmegen, The Netherlands; e-mail: t.schermer@elg.umcn.nl

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Response

To the Editor:

I am happy that the Point/Counterpoint Editorial (November 2010) have stirred interest in the medical community regarding the use of spirometry to define COPD. In their letter, Drs Robberts and Schermer present support to both positions expressed in the Point/Counterpoint Editorials.

First, they agree that the health-care provider is the person who decides the clinical significance of an observed test result, a central argument in our thesis. In this context, a cutoff value for any test serves only as a guide, as it does for all of the supportive tests in medicine. Even though the authors of the letter would like to avoid the comparison, how would they interpret a hemoglobin value of 12.9 mg/dL in a 75-year-old man? Would they label the patient as having anemia? Or, for that matter, an arterial BP of 140/90 mm Hg in an 82-year-old woman? In both instances, the health practitioner uses the clinical context to determine whether the test result supports (and I emphasize the word support) a clinical diagnosis. Agreed-upon operational definitions are by and large used in studies to avoid subjective misclassification. In this regard, the simpler the definition, the more likely it will be accepted and shared.

Second, the authors of the letter support the argument presented by Enright and Brusasco that the predictive value is better because it corrects the “overdiagnosis” in elderly subjects who would not have COPD. They base the argument on their experience in many of the studies. This criterion allowed inclusion of a broad range of severity categories (including those with borderline or no airway obstruction). But it is a mistake to consider the inclusion criteria as providing evidence for a definition of clinically important COPD, especially when diagnosing and treating individual patients. Note that the number of subjects in some of these studies as providing evidence for a definition of clinically important COPD, especially when diagnosing and treating individual patients. Note that the number of subjects in some of these studies with the ratio < 0.70 but above the fifth percentile lower limit of normal was negligible—for example, 13 out of 718, or 1.8%. In the past, the investigators in large, multicenter, randomized, clinical trials considered change in FEV1/FVC ratio as an inclusion criterion, and we participated favorably in some of them. This criterion allowed inclusion of a broad range of smokers, with lung function ranging from normal (FEV1 above the fifth percentile) to severely compromised, which increased the statistical power to demonstrate differences in outcome between severity categories (including those with borderline or no airflow obstruction). But it is a mistake to consider the inclusion criteria of these studies as providing evidence for a definition of clinically important COPD, especially when diagnosing and treating individual patients. Note that the number of subjects in some of these studies with the ratio < 0.70 but above the fifth percentile lower limit of normal was negligible—for example, 13 out of 718, or 1.8%.

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We thank Dr Fabbri for his letter, which gives us the opportunity to further clarify our view on this issue without fear of self-plagiarism, a term that includes “text recycling” but not opinions consistently repeated on different occasions. We acknowledge the merit of the GOLD (Global Initiative for Chronic Obstructive Lung Disease) initiative for COPD, in providing a “living document” that is updated every year in response to newly published evidence. Certainly, the majority of the GOLD guideline is based on good evidence, but its current recommendation to use the faulty FEV1/FVC ratio to define airflow obstruction is not and, thus, should be changed soon.

During the past 3 decades, several clinical trials have used the fixed FEV1/FVC ratio as an inclusion criterion, and we participated in some of them. This criterion allowed inclusion of a broad range of smokers, with lung function ranging from normal (FEV1 above the fifth percentile) to severely compromised, which increased the statistical power to demonstrate differences in outcome between severity categories (including those with borderline or no airflow obstruction). But it is a mistake to consider the inclusion criteria of these studies as providing evidence for a definition of clinically important COPD, especially when diagnosing and treating individual patients. Note that the number of subjects in some of these studies with the ratio < 0.70 but above the fifth percentile lower limit of normal was negligible—for example, 13 out of 718, or 1.8%.

In the past, the investigators in large, multicenter, randomized, clinical trials considered change in FEV1, an index of the natural history of COPD, as the primary outcome measure. Only after these randomized clinical trials proved that available inhaled drugs were not effective in slowing the loss of FEV1, were alternate COPD outcome measures, such as improved quality of life or reductions in outpatient exacerbations, proposed.

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