

Don't Use the Flawed Fixed Ratio to Diagnosis COPD

Massive programs are underway to extend the use of expensive inhalers from the 5 percent of susceptible smokers who have lost more than half of their lung function due to chronic obstructive pulmonary disease (COPD) (Global Initiative for Chronic Lung Disease [GOLD] stages III and IV) to the much larger group with borderline to mild airway obstruction (GOLD stages I and II). The financial incentives are huge, since the expanding worldwide market for COPD inhalers is currently over 5 billion dollars per year, with a profit margin over 20%. The companies that manufacture and market these inhalers are thus eager to provide very generous "unrestricted" educational grants to professional organizations and key opinion leaders for COPD symposia, COPD guidelines committees, COPD awareness programs, and spirometry supplies.

In the context of these programs, we read the excellent review of "Spirometry for the Diagnosis and Management of COPD"¹ with considerable interest. We worry that a mixed message was given regarding the seriously flawed fixed ratio of forced expiratory volume in the first second to forced vital capacity (FEV_1/FVC) < 0.70, advocated since 2001 by the industry-sponsored GOLD committee for defining airway obstruction. There is no disagreement among respiratory physiologists on this issue,² and the National Lung Health Education Program (NLHEP) has never advocated the use of a fixed ratio, since more than 50 studies have demonstrated that the ratio falls with normal aging in healthy never-smokers.³ There is no reason to accept a 50% false positive rate when testing older people using the "easy to remember" fixed ratio, since even inexpensive portable spirometers can calculate the true lower limit of the normal range.

Although smokers with respiratory symptoms are "at risk" of developing COPD, GOLD stage 0 was eliminated in 2006 because normal spirometry rules out COPD.

In our opinion, the GOLD stage I "mild" category should also be eliminated, since there is no evidence that smokers with a borderline to mildly low FEV_1 (> 70% of predicted) are at an increased risk for morbidity or mortality from respiratory disease.⁴ There is confusion because even a mildly low FEV_1 or FVC increases the risk of death from cardiovascular disease. However, this increased risk appears to be due to abdominal obesity, not COPD.⁵ Prescribing a long-acting bronchodilator for these patients has the potential to cause more harm than good.⁶

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Dr. Enright has disclosed a relationship with Pfizer. Dr Ruppel has disclosed no conflicts of interest.

REFERENCES

1. MacIntyre NR. Spirometry for the diagnosis and management of chronic obstructive pulmonary disease. *Respir Care* 2009;54(8):1050-1057.
2. Pellegrino R, Brusasco V, Viegi G, Crapo RO, Burgos F, Casaburi R, et al. Definition of COPD: based on evidence or opinion? *Eur Respir J* 2008;31(3):681-682.
3. Swanney MP, Ruppel G, Enright PL, Pedersen OF, Crapo RO, Miller MR, et al. Using the lower limit of normal for the FEV_1/FVC ratio reduces the misclassification of airway obstruction. *Thorax* 2008;63(12):1046-1051.
4. Vollmer WM, Gíslason T, Burney P, Enright PL, Gulsvik A, Kocabas A, Buist AS.

Comparison of spirometry criteria for the diagnosis of COPD: results from the BOLD Study. *Eur Respir J* 2009;34(3):588-597.

5. Enright P. Overindulgence --> overweight --> reduced vital capacity --> reduced longevity. *Am J Respir Crit Care Med* 2009;179(6):432-433.
6. Enright P. Don't prescribe tiotropium for smokers with an FEV_1 above 60% predicted. *Prim Care Respir J* 2009;18(2):119-120.

The author responds:

I thank Drs Enright and Ruppel for their comments and agree strongly that the use of the fixed FEV_1/FVC ratio cutoff of 0.70 for diagnosing airway obstruction is too simplistic and will both under-diagnose airway obstruction in younger populations and over-diagnose airway obstruction in older populations. As I pointed out in my paper, large organizations such as GOLD have stuck to this fixed ratio for simplicity. Like Drs Enright and Ruppel, however, I disagree with this decision and certainly did not intend to send a "mixed message."

Drs Enright and Ruppel raise another important point—the notion that mass spirometry screening could lead to inappropriate over-prescription of bronchodilator therapy. As noted in my paper, the United States Agency for Healthcare Research and Quality (AHRQ) has studied this very issue. Their results showed that screening spirometry could indeed lead to substantial increases in bronchodilator therapy. However, the benefits of this would only be small reductions in COPD exacerbations in only a few of the treated patients. The AHRQ thus went on to conclude that this marginal benefit was not worth the exorbitant costs.

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