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LETTER TO THE EDITOR

Spirometry standards and FEV_1/FVC repeatability

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Dear Sir,

I read with interest the recent letter by Fletcher & Loveridge on within-session repeatability spirometry standards for FEV_1 and FVC and the reply by my co-authors[1] of the Spirometry Standards paper published in this journal last September.[2]

I think the reply by my co-authors shows clearly that there is complete confusion over "repeatability" and the "average within-individual repeatability". In practice, these are often assumed to be the same thing by most users of spirometry. What the practitioner wants to know is; "How many spirometry efforts do I need to make to ensure I get a representative value of FEV_1 or FVC for my patient?". Clearly this must relate to the number of efforts that the patient has to make and therefore introduces an acceptability criteria that two blows (of three acceptable attempts) should be within 100mL (ARTP)[3] or 150mL (ATS/ERS).[4] As the reply states, we can usually get this within-individual repeatability down to 50-60mL, so 100mL is actually fairly lenient but practical. But is it always right?

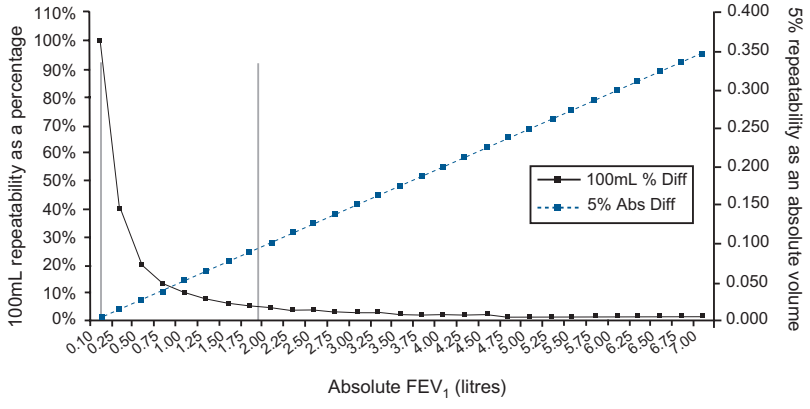
The ATS/ERS 2005 guidelines[4] actually state that the 150mL cut-off should be used for FEV_1 and FVC generally, but that 100mL should be used when the volumes are below 1.00 L (in agreement with the ARTP value). If we explore the rationale behind these recommendations we can begin to understand why we may need to be more flexible in our approach.

To illustrate these issues, Figure 1 shows the 100mL repeatability method (solid squares & line) as a percentage of the measurement made, and the absolute value of the 5% repeatability (broken line/open squares) across the working range of spirometry (0 – 7.0 litres). The two perpendicular lines in Figure 1 indicate the upper and lower ranges of FEV_1 reported in two large COPD trials (TORCH[5] and UPLIFT[6]) and show how important it is to establish the correct recommendation not just for COPD but for detecting all lung diseases.

Taking the 100 ML repeatability value; below 1 litre, the percentage value of the repeatability gets unacceptably large. However, with volumes at 1.00 litre and below, the 5% absolute value for repeatability gets sequentially smaller as the FEV_1 reduces. By using the absolute 100mL (i.e. "whichever is greater") at these levels, the percentage error increases, although the absolute difference remains constant. Above 2.00 litres, the 5% error becomes larger than the 100mL repeatability, so "whichever is smaller" should be applied.

I entirely agree that there are pitfalls in using a fixed value and a percentage value of

Figure 1. Errors in repeatability of spirometry.



repeatability. This raises the question of the logic of adopting 100mL or 5% whichever is greatest. Whilst it may be acceptable with total volumes above about 2.00 litres, it should actually be "whichever is smaller" below this value. However, for the purposes of detecting lung disease, as FEV_1 decreases, the percentage value makes more sense over the fixed 100mL.

My co-authors comment at the end of their reply that they look for evidence that "100 ml is both a realistic and achievable standard" and I suggest they need look no further than their local lung function department or within their own practice, where their nurses may have the appropriate training to achieve this standard. Further evidence will inevitably follow to verify using this tighter 100mL standard from a variety of on-going trials.

On the same subject, Enright's independent letter[7] defends the softer 150mL target without referral to the Fletcher & Loveridge letter. I have to question his conclusion that the 150mL repeatability is acceptable since the two large studies he cites[8,9] were performed in the USA prior to the ATS/ERS 2005 Guidelines[4] when the ATS criteria for acceptability was only 200mL.[10] Clearly, staff operating spirometers under these more lax standards may only have achieved repeatability within 150mL because there was a less stringent target set. We have years of practical experience of monitoring quality control in spirometry by highly trained physiologists and these show that in healthy subjects, repeatability for both FEV_1 and FVC in biological controls is often between 30-50mL.[9] Therefore, by setting 100mL as the repeatability value we are allowing less experienced primary care staff – who may generally perform 5-15 spirometry tests each week (compared to the 40-100 measured by a physiologist in a dedicated lung function department) – to achieve this standard.[11]

When the BTS COPD Guidelines were launched in the UK in 1994[12] the protagonists insisted that "spirometry can be measured relatively easily and quickly and at all stages of the disease" which we feel implied that lower standards of spirometry were required to allow uptake of spirometry in clinical practice. Despite protestations from experts in respiratory physiology at the time, spirometry blundered on in primary care until eventually, through good training and the realisation that spirometry is not easy, standards have improved. However, as the evidence mounts[13-15] for the requirement of targeted spirometry in patients likely to have COPD, it is no longer satisfactory to accept those lower standards and the development of two-tiers of spirometry – one for case-finding and one for diagnostic quality.

I have aired my concerns for many years that I feel "office spirometry" should be limited.[16] Indeed, this was the motivation behind the Spirometry Standards document[2] that my co-authors and I toiled for many months to write. As authors, we all aired our opinions – from the idealistic to the realistic – but compromising on standards may not do patients or our services justice in an increasingly fiscally-pressured health service. The Spirometry Standards document certainly made some very bold and brave decisions as regards standard-setting, adopting the lower limit of normal (LLN), and suggesting practical guidelines for the provision of spirometry services.[2]

I am actually impressed by the grading criteria alluded to in Enright's letter,[7] and provided that this is used as an internal audit tool to improve spirometry practice I think it has a positive role to play in driving up standards within a spirometry service. However, this artificial barrier in quality between technologists/physiologists scoring A&B, and practitioners in other settings scoring C to F, not only undermines some of the excellent spirometry performed by our trained practice nurses, but also demeans the value of making the measurement at all. I strongly disagree that "in some settings optimal spirometry is not necessary". This is like saying that provided a blood glucose meter is accurate to within 5-10mmol/L then diabetic patients can monitor their diabetes control perfectly well at home…

The spirometry test is rapidly becoming the gateway to a stream of diagnostic tests including formal lung function tests, a chest x-ray, a hospital out-patient consultation, and even a therapeutic trial of inhaled bronchodilators. The unnecessary cost of all this intervention (£400-£600) on the basis of poor spirometry technique is a reality we face every week in the lung function department and could be avoided by use of high quality spirometry in a variety of settings every time.

There is a caveat to this high quality repeatable standard; in a limited number of patients the lower grading of the spirometry (i.e. poor repeatability) can often indicate a clinically significant problem[17] especially in severely sick patients. I agree with Enright that more research is needed to verify how poor "poor quality" needs to be, but also we need to investigate whether the use of just FEV_1 together with an appropriate questionnaire is enough to detect patients with early COPD so that interventions can start early enough (usually smoking cessation). The evidence so far suggests that perhaps opportunistic spirometry in primary care does not detect COPD whether training (and presumably working to standards) takes place or not.[18] However, until the comparison is made between "cheap and dirty" case-finding spirometry with quality diagnostic spirometry, we will not be sure that diagnostic quality spirometry is both clinically and financially effective. Cynics would say; abandon the spirometry altogether and just focus on smoking cessation alone…

The mantra of pulmonary function experts may be 'minimise misclassification',[7] but I would suggest that we may want to maximise accurate measurement first. The evidence for the use of 100mL repeatability in primary care spirometry will undoubtedly accrue as this issue is further debated. However, I feel that the ARTP 1994 standard of "100mL or 5% whichever is the greater"[3] should still be used, but with the caveats mentioned above (i.e. "whichever is smaller above 2.00 litres" and whichever is greater below 1.00 litre).

Perhaps it depends on whether we see the spirometer as being half full or half empty…

Conflict of interest declaration

The author has no conflicts of interest on this topic.

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