

PRO/CON DEBATE

Limitations to spirometry being performed in ‘the office’

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Introduction

The use of spirometry is increasing as the measurements move from the lung function laboratory to the Primary Care setting or the so-called ‘office’.^{1–4} There is also published evidence of disparity between practice and hospital services^{5,6} the quality of spirometry performed^{5,7} and the level of interpretation skills of practice staff. There is a recognized need to increase training in spirometry knowledge and general understanding.⁸ It is claimed that specialist services improve diagnostic accuracy⁹ as well as diagnostic interpretation.¹⁰ Overall, the concern about the quality and delivery of spirometry is a widespread issue.^{5,11,12}

There are other examples of diagnostic tests that have made this transition in recent decades; the blood glucose measurement in diabetes,¹³ the cholesterol test in obesity¹⁴ and the electrocardiogram in heart disease.¹⁵ All of these examples went through a period of initial take-up in specialist practices only, before a technological advancement and commercial development made testing simpler, cheaper and more widely available. For example, early blood glucose meters were bulky, unreliable and needed strict protocols for users to get reliable results. Eventually with further device refinement, improved technology and operator training, blood glucose meters became widely available so that not only did they get used in doctor’s ‘offices’, but soon patient’s were able to test their own samples at home.

So why didn’t this transition from laboratory to office (or even ‘kitchen’) happen for lung function measurements 30 years ago? Well in some way it did, in that the development of the mini-Wright peak flow meter and asthma guidelines took peak flow measurement out of the hospital into the ‘office’ and eventually in to the home. Again it required a technological development – the mini-Wright device and the development of ‘asthma nurses’ to ensure the measurement was made correctly

before mass production and use of the peak flow measurement became widely available in primary care. Now modern peak flow meters are generally electronic with data storage facilities and some algorithm to ensure acceptability of measurements within either ATS or ERS standards. So why has spirometry not taken off in the same way?

The fundamental difference between respiratory physiological diagnostics and either physiological diagnostics (ECG, oximetry) or biomedical diagnostics (blood glucose, cholesterol etc.) is that spirometry by its very nature requires maximum patient effort, operator motivated results and careful monitoring of both subject and equipment to make sure that the efforts are reliable reproducible and accurate. Whereas the peak flow is over in about 100 milliseconds, spirometry obviously requires a sustained effort for up to 12 seconds or longer. Let us examine these issues in more detail.

The limitations of spirometry are:

Operator

- obtaining maximal reproducible manoeuvres (from often sick patients);
- operator training;
- operator understanding, experience and skill;
- operator being able to detect subject warning signs.

Subject

- able to understand what they have to do;
- able to perform the measurement reproducibly;
- able to repeat the test with corrections to technique.

Equipment

- measuring FEV₁, FVC (and VC) accurately and reliably;
- acceptability of measurement within standards;

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- software algorithms able to select and store the best values;
- quality assurance of the device over time (verification/calibration, biological controls).

Operator/subject errors

It is difficult to separate the operator and subject errors because each depends on the other to perform the test reliably and accurately. Evidence of variation in spirometry in untrained subjects is well documented.^{5,7}

The nature of spirometry requires that the subjects make maximal efforts. The FEV₁ and FVC are the essential parameters in spirometry with the 'F' naturally referring to 'forced' manoeuvres. And therein lies the problem. To obtain an acceptable FVC the following steps have to be accomplished; i) maximal inspiration to true TLC, ii) no pause at TLC, iii) forced maximum expiration to residual volume, iv) no slow start or pauses, v) no coughs, 'easing off' or occluding the airway, vi) no early cessation of effort and vii) reproducible efforts. Training operators to ensure the patients perform this sequence correctly is the main limitation to spirometry being adopted widely and reliably. Most lung function departments have these adequately trained and experienced staff available and practice enough to keep skill levels high.

The FEV₁, should be reproducible and accurate if the whole FVC manoeuvre is performed correctly and within standards. The question is which standards? Table 1 shows the current criteria which are widely used, but there is as yet no consensus as to which should be acceptable.

There is therefore the dilemma that although the operator may be well trained and able to use a multitude of skills, (language, vocabulary, voice techniques, motivation, body language etc.) to get the subject to perform the test correctly, the subject must understand what to do, how to do it, when to perform the manoeuvres and also be physically able to perform the test.

Whilst forced manoeuvres have their own problems, there are further issues with the relaxed vital capacity manoeuvre. The use of VC to assess lung function in

COPD is often underestimated by COPD guidelines and largely because in severe small airways obstruction the VC can be poorly reproducible and may require long rests between efforts, thus increasing testing time. To this end, believers in office spirometry have adopted the use of the FEV₆, a six second forced manoeuvre, as a standardized measure of expired lung volume. Whilst FEV₆ may certainly have a place and could form the cornerstone of office spirometry it has its limitations also. FEV₆ could still miss the so-called 'volume responders' to bronchodilatation, who hardly change FEV₆, but may have increases in VC of 50% from baseline albeit with and increased FET.

Equipment

One of the greatest stumbling blocks to Office Spirometry currently has to be the capability, reliability and accuracy of spirometers themselves

There are numerous papers that show the size of the difference between spirometers.¹⁶⁻¹⁹ Determining which are correct and reliable remains a major problem in using office spirometers widely. Many spirometers have passed the ATS Test rig criteria, but still vary by a large amount.^{20,21} How can the software for the equipment ensure that the main criteria for acceptable spirometry are met? Consider, the seven main issues for quality in spirometry: i) maximal inspiration to true TLC; ii) no pause at TLC; iii) forced maximum expiration to residual volume; iv) no slow start or pauses; v) no coughs, 'easing off' or occluding the airway; vi) no early cessation of effort; and vii) reproducible efforts.

It is possible to envisage ways that technology can beat some of these stumbling blocks. Whilst software algorithms can and have been written to achieve the latter four criteria, it is difficult to ensure that the first three are upheld. Ultimately these three quality issues can only be truly overcome by a well-trained operator measuring a well-instructed subject.

Interpretative software?

The use of interpretative software should currently be discouraged because often a diagnosis and report needs more clinical details than a spirometry test can provide. Many algorithms for acceptability of data are either too stringent or not stringent enough and therefore produce errors in interpretation.

Instead the use of on-line quality assurance and interpretation by trained professionals via internet and phone links should be encouraged in either real-time or with a delay of hours or days. Possible

Table 1 Criteria for acceptable spirometry

	No. efforts	Exhale time	Values	Criteria
ERS 1993	Three minimum	Six seconds minimum	First three technically satisfactory	Within 5% or 100 mL
ATS 1994	Eight maximum	20 seconds maximum	Largest two technically satisfactory	Within 200 mL

outcomes should include: i) technically unacceptable; ii) technically acceptable but probably submaximal; iii) technically acceptable but incomplete efforts; and iv) technically acceptable.

The current limitations to service issues that need resolving are: i) accurate and reliable equipment; ii) quality assurance; iii) algorithms for acceptability of data too stringent/not stringent enough; iv) repeatable efforts; and v) motivation for patients.

The use of screening spirometry whilst simple in concept has major problems when put in to practice. There is a danger that the 'number in a box' phenomenon (e.g., the UK GMS2 contract where only an FEV₁ value is required) leads to poor standards and sloppy practice rather than paying attention to quality and standards. Office spirometry also suggests the introduction of double standards in spirometry by having different levels of acceptability for 'screening' versus 'monitoring' spirometry. There is little point in having screening ECG, cholesterol or blood glucose if the measurements are inherently unreliable, so why should spirometry be the exception?

Also office spirometry should not be an excuse for proper standards of service including infection control, adequately trained staff and quality control procedures to be ignored. Accurate costing of office spirometry should include the resources to cover all these aspects of service and not just be seen as the capital cost of the spirometer plus a few consumables.

Whilst office spirometry can provide the opportunity to detect early lung disease by being widely available, there is no reason why more conventional spirometry services cannot be resourced to intervene at an early stage in lung disease too.

Conclusions

Office spirometry is achievable and has a place but certain criteria need to be met in terms of equipment and software, operator training and contraindications for certain patients.

Whilst office spirometry is feasible we are many years off that goal. Certainly the use of spirometry in primary care is essential, but this needs some degree of regulation of practice to ensure competence is adequate.

The continual dilemma of volume versus quality is a key issue. Is a large amount of inept spirometry going to raise awareness of this valuable technique, or is poor spirometry going to lead to loss of credibility of the measurement?

The future requires either some more passive tests of lung function (e.g., impulse oscillometry) or the development of more sophisticated technology (e.g.,

negative expiratory pressure) with appropriate fail-safe algorithms. Until then office spirometry should continue to be developed but not yet widely adopted.

Declaration of interest

The author of this paper has no conflict of interest to declare.

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