Quality assessment pathway for respiratory oscillometry

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To the Editor:

There is strong evidence to support the addition of respiratory oscillometry to standard lung function testing. The key parameters are sensitive in identifying the presence and severity of airways disease [1], and clinically meaningful cut-offs have been established to identify bronchodilator response [2] and bronchial hyperresponsiveness [3-6] independent of spirometry. While clinical uptake is increasing with the availability of commercial devices, oscillometry is yet to be widely adopted as a standard test. This has been in part due to a lack of standardisation in equipment specifications and inconsistent terminology, but also human-related factors such as measurement protocols and objective quality control. The recently published international technical standards [7] have partly addressed most of these issues, and the development of global reference equations are currently in progress. Nevertheless, there remains a strong need to develop standard methods to optimise measurement quality and operator competency.

Operator oversight, feedback and frequency of testing is known to significantly improve spirometry quality [8]. Although oscillometry measurements are collected during resting tidal breathing, it is a misconception that less quality control surveillance is required in comparison to forced manoeuvres. We present a quality assessment pathway based on current technical standards for oscillometry [7], established frameworks for spirometry [9], and over ten years’ experience with clinical oscillometry testing (Figure 1). Similar to other tests of lung function, ideal levels of test quality are not always achievable, thus we propose a quality grading system based on technical acceptability and within-session coefficient of variability (CoV). The grades range from the best quality achievable that offers the highest level of confidence, to the minimum quality that may still provide clinical utility.

In preparation for the test, the technical standards recommend daily verification using an appropriate test load and also provide a list of minimum instructions for patients prior to testing [7]. In the measurement phase, the goal is to obtain at least three technically acceptable individual trials (or ‘replicates’). While not specified in the technical standards, we suggest that no more than eight trials be collected, consistent with spirometry [9] and the observation that a plateau for CoV is usually reached at this point [10].

Grading is applied in the post-processing phase and is dependent on the number of technically acceptable trials achieved and within-session CoV of resistance at 5 Hz (R5). The
highest quality grading A, represents the current technical standards recommendation of at least three acceptable trials with a CoV≤10% [7]. However, there is increasing evidence that higher within- and between-session variabilities are inherent to airways disease, unaffected by the number of trials completed. The 95\textsuperscript{th} centile for within-session CoV for asthma and COPD during stable disease reach up to 13% and 18%, respectively [10]. Thus, we assign 15% and 20% CoV as Grades B and C, respectively. Grades D and E represent scenarios where either variability is further increased, or the recommended number of technically acceptable trials are not attained. For Grade D, our suggested upper CoV limit of 40% is based on our analysis of previous data collected during exacerbations of COPD [11], where we calculated the 95\textsuperscript{th} percentile for CoV as 40.6%. This should be re-evaluated when further evidence is available. We suggest that Grades D and E still be reportable but flagged, and Grade F (when the above criteria are not met) be unreportable.

Importantly, within-session CoV is not considered for individual trial acceptability, but rather for final quality grading. This eliminates operator bias, where trials may be spuriously chosen to reduce CoV. Careful vetting focussing on technical acceptability rather than CoV at the end of each trial allows the opportunity to modify patient instruction to improve technique, if required.

We have only incorporated the within-session CoV for R5 for quality assurance, as per the technical standards. Although the upper limits of reactance have been published in health and disease, CoV of reactance can be highly variable and difficult to interpret owing to its proximity to zero thus may not be suitable as a quality control measure. Examination of the frequency spectra may also allow the operator to compare impedances of individual trials across frequencies to assess outlying trials. However, this feature is not universally available, nor is it applicable to single-frequency systems.

This pathway and grading system is proposed for use within the clinical or research laboratory setting. It is worth noting that for home telemonitoring or field applications, the technical standards allow for the measurement of a single, longer recording. In such cases, other quality control measures may need to be applied, e.g. the within-trial variability. In addition, the recommended cut-off for within-session CoV for children is higher (15%), and the effect of disease on variability relatively unclear. Hence, the present framework can only be recommended for adults.
Our proposal to report testing quality for respiratory oscillometry using a standardised, regimented pathway and grading system aims to operationalise the ideal recommendations set out in the technical standards. It serves as a framework for operator training, compliance, and standardised assessment with feedback, which is known to improve lung function session quality in general. Validation studies are now required to assess the utility of this pathway across clinical and primary care laboratories, and broad community groups.

References:

Figure legend:

Figure 1. Quality assessment pathway for respiratory oscillometry

*Standard quality session. ^Unreportable. †Grade D and E to be interpreted with caution.
FRC; functional residual capacity, CoV; coefficient of variation (for ≥2 trials), R5; resistance at 5Hz
Reinforce good technique and repeat trial when unacceptable and/or spectra variable

Visual check of individual trials:
Manual exclusion of artefact/outliers not filtered by software

From the acceptable trials, report:
- Mean absolute and z-score of key parameters
- CoV of R5 to reflect session repeatability
- Spectra (frequency) graphic if available
- Test quality Grade

Clinical interpretation†

<table>
<thead>
<tr>
<th>Grade</th>
<th># of acceptable trials</th>
<th>CoV R5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>A*</td>
<td>≥ 3</td>
<td>≤ 10</td>
</tr>
<tr>
<td>B</td>
<td>≥ 3</td>
<td>11-15</td>
</tr>
<tr>
<td>C</td>
<td>≥ 3</td>
<td>16-20</td>
</tr>
<tr>
<td>D</td>
<td>≥ 3</td>
<td>&gt;20 and ≤40</td>
</tr>
<tr>
<td>E</td>
<td>2</td>
<td>≤ 20</td>
</tr>
<tr>
<td>F^</td>
<td>≤ 2</td>
<td>&gt;20</td>
</tr>
<tr>
<td></td>
<td>≥ 3</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>

Preparation
- Daily device test load verification and signal selection
  - Provided patient instruction
  - Ensure correct patient position

Measurement
- Patient acclimatised to stable, natural breathing on mouthpiece prior to data acquisition
  - Perform at least three acceptable 30 second trials
  - Real-time display and patient are constantly monitored to ensure:
    - Stable, natural breathing (near approx. FRC)
    - ≥3 breaths free of artefact
    - Such as; Leak, Swallow/glottal closure, Cough, Irregular or active/forced breathing, Negative resistance values
  - Reinforce good technique and repeat trial when unacceptable and/or spectra variable

Post processing
- Visual check of individual trials:
  - Manual exclusion of artefact/outliers not filtered by software
  - From the acceptable trials, report:
    - Mean absolute and z-score of key parameters
    - CoV of R5 to reflect session repeatability
    - Spectra (frequency) graphic if available
    - Test quality Grade

Clinical interpretation†