Assessment of a commercially available cough counter in healthy subjects

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Introduction and objective

• Reliable cough quantification could qualify as a relevant outcome in CF clinical research but is technically challenging.
• Preliminary assessment of a commercially available cough counter (PulmoTrack WHolter⁶, KarlMedSonix, Haifa, Israel) in CF patients yielded disappointing results in our Unit, as the device missed more than one third of cough components. The only published validation study of this device has been performed by its developers on 12 healthy subjects coughing voluntarily. Sensitivity and specificity > 90% under most circumstances were claimed.¹
• The aim of the study was to verify the accuracy of the PulmoTrack WHolter⁶ in detecting voluntary cough sounds in healthy subjects while rejecting other sounds with similar characteristics.

Results

• In total, each subject executed 54 coughs events, 72 coughs components, 9 forced expiratory, 15 throat clearings, 42 speech and 9 bursts of laugh.
• An overall sensitivity of 66±28 % and 70±26 % was observed for cough events and components respectively. Corresponding values for specificity were 95±6 % and 89±16 %.
• False positives were more likely for cough components (10±16 %) than for cough events (5±6 %) [Table 2]. Most false positives were related to throat clearing or laughing [Figure 1].
• Intersubject variability of cough detection by KS was high. More than 30% of cough components were missed in 4/12 volunteers. [Figure 2]
• Cough from low or intermediate volumes was less often detected than cough from high volume, though the difference was not significant (p=0.012) [Figure 3].

Methods

• Study population
12 healthy adults (9F/3M, mean age ± SD: 28.3 ± 6.9) without respiratory infection at the time of the study.
• Material & Methods
The participants wore the KarlMedSonix (KS) CoughCOUNTTM while they reproduced different sounds according to a detailed protocol [Table 1]. Recordings were made while each subject was (a) sitting, (b) sitting in a noisy environment, (c) climbing/going down of a stepladder. A database of 1764 sounds and 120 minutes of recordings was obtained. The device was connected to two contact microphones (on the trachea and chest wall), one audio microphone and a pneumogram belt.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>High volume cough</th>
<th>Medium volume cough</th>
<th>Low volume cough</th>
<th>Throat clearing</th>
<th>Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Component</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

Recording were listened and annotated by two trained observers. Their consensus provided the gold standard against which the automatic reading of the KS was then compared. Coughs were counted in terms of events (defined as breaths containing at least one explosive phase) and components (number of explosive phases).

Sensitivity and specificity of cough detection by the device were then calculated.

Discussion and conclusion

Though both studies focused to healthy subjects, the results of the present work differ from those of the preliminary KS validation study¹. We found significantly lower sensitivities for events and components detection [Table 3]. The protocols of the 2 studies were not identical as we investigated cough from different volumes which seems meaningful and has been used by the developers of the best studied device (VitaloAK™) to calibrate their system. In addition, throat clearings which are likely to be frequent among expectorating patients were included among non-cough sounds in our database while Vriel et al. excluded them as they knew that their algorithm was not designed to discriminate them from coughs.

In conclusion, we were unable to confirm the high sensitivity claimed for voluntary cough detection in healthy volunteers by the PulmoTrack WHolter⁶. The algorithms and/or sensors of this device should be improved. In addition, cough counters should also be validated in patients with various diseases.

¹Vriel et al. Validation of an ambulatory cough detection and counting application using voluntary cough under different conditions. Cough 2010; 6:3. doi: 10.1186/1745-9974-6-3

Table 1: Detailed protocol

Table 2: Performance of the KS

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
<th>False positive, %</th>
<th>False negative, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>KS</td>
<td>55</td>
<td>77</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td>Healthy subjects</td>
<td>58</td>
<td>90</td>
<td>7</td>
<td>11</td>
</tr>
</tbody>
</table>

Table 3: Sensitivity (SN) and specificity (SP) of our study (1) and of Vriel et al. (2) study

<table>
<thead>
<tr>
<th>Tests</th>
<th>SN (Mean±SD)</th>
<th>SP (Mean±SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy subjects</td>
<td>58±6</td>
<td>90±3</td>
<td>0.0011</td>
</tr>
<tr>
<td>KS</td>
<td>55±15</td>
<td>77±5</td>
<td>0.0017</td>
</tr>
</tbody>
</table>

1 Healthy subject
2 KS