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 WHolter™, KarmelSonix, 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 in 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 WHolter™ in detecting voluntary cough sounds in healthy subjects while rejecting other sounds with similar characteristics.

Methods

- **Study population**

12 healthy adults (9F/3M, mean age ± SD: 28.3 y ± 0.9) without respiratory infection at the time of the study.

- **Material & Methods**

The participants wore the KarmelSonix (KS) CoughCOUNT™ 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.

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.

Table 1: Detailed protocol

Protocol	n
High volume cough	5
Middle volume cough	5
Low volume cough	5
Three events composed by three components	3 events & 9 components
Forced expiratory	3
Throat clearing	5
Speaking	14
Laughing	3

Results

- In total, each subject executed 54 coughs events, 72 coughs components, 9 forced expiratory, 15 throats clearing, 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 coughs components (10±16 %) than for coughs events (5±6 %) [Table 2]. Most false positives were related to throat clearing or laughing [Figure 1].
- Interindividual 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= 0.112). [Figure 3]

Table 2: Performance of the KS

Subjects	Sensitivity, %		Specificity, %		False positive, %		False negative, %	
N°	Events	Components	Events	Components	Events	Components	Events	Components
1	65	72	96	44	4	56	35	28
2	100	100	96	94	4	6	0	0
3	89	89	98	99	2	1	11	11
4	80	85	100	100	0	0	20	15
5	91	93	89	86	11	14	9	7
6	68	69	100	99	0	1	31	30
7	24	38	100	100	0	0	76	68
8	74	78	96	96	4	4	26	21
9	22	19	96	97	4	3	78	80
10	98	99	78	79	20	21	2	1
11	33	36	100	97	0	3	67	64
12	53	62	91	83	9	17	44	39
Mean	66	70	95	89	5	10	33	30
SD	28	26	6	16	6	16	28	27

Figure 1: Selected non-cough sounds and corresponding percentage of false positives

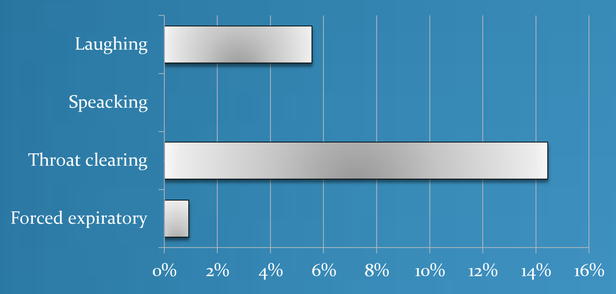


Figure 2: Percentage of false negative components

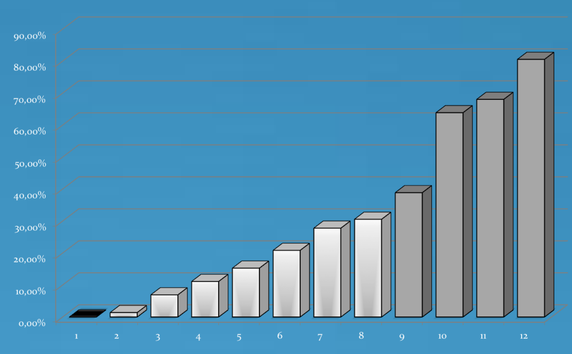
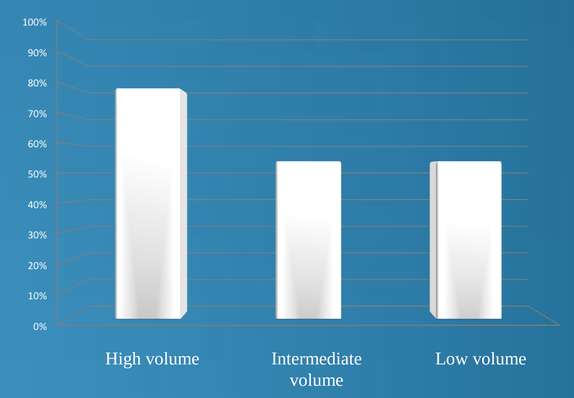


Figure 3: Detection of cough from 3 different lung volumes



Discussion and conclusion

Though both studies focused to healthy subjects, the results of the present work differ from those of the preliminary KS validation study [1]. 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 (VitaloJAK™) to calibrate their system.
In addition, throat clearing which are likely to be frequent among expectorating patients were included among non-cough sounds in our database while Vizel et al. excluded them as they knew that their algorithm was not designed to discriminate them from coughs.

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

	1		2		p-value	
	Events	Components	Events	Components	Events	Components
SN, median [range]%	71.50[22.22-100]	75.50[36.11-100]	95.50[89-100]	91[80-98]	0.003*	0.039*
SP, mean±SD%	95.17±5.95	89.50±15.98	93.42±3.58	93.42±3.58	0.392‡	0.416‡

* Kolmogorov-Sminorv test
‡ Student t test

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

[1]Vizel 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