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Can Passive Cough Monitoring Predict COPD Exacerbations?

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ABSTRACT

Purpose: Validation of an alert mechanism for COPD exacerbations based on coughing detected by a stationary unobtrusive nighttime monitor.

Methods: This prospective double-blind longitudinal study of cough monitoring included 40 chronic obstructive pulmonary disease (COPD) patients. Participants underwent cough monitoring and completed a daily questionnaire for 12 weeks. If no exacerbation occurred within that period patients were asked to continue being monitored for a further 12 weeks. The automated system identified deteriorating trends in cough based on a personalized cough classifier and the alerts were compared with patient reported exacerbation onsets.

Results: Thirty-eight patients [median age 72 (range 57–84)], median FEV-1% predicted 43% (range 20–106%) completed the study and had 41 exacerbations over a total of 3981 days. For 32 patients, the cough monitor data allowed classifier personalization, trend analysis, and alert generation. Based on the trend data, it is estimated that ~30% of exacerbations are not associated with an increase in cough. The alert mechanism flagged 59% of the exacerbations. For the cases with alerts preceding the onset, the associated lead time was 4 days or more.

Conclusion: Though based on a single variable only, the cough-based alert system captured more than half of the exacerbations in a passive, free-living scenario. No adherence issues were reported, and patients confirmed the unobtrusive and hassle-free nature of the approach.

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KEYWORDS
COPD; exacerbation; alert system; automated cough count; telehealth

1. Introduction

Monitoring of chronic diseases is often viewed as a way to improve health care outcomes and health care costs by enabling early intervention to prevent or postpone more serious and costly consequences. The success of monitoring depends on the relevance and trustworthiness of the collected data. Since questionnaire data is often hampered by subjectiveness (due to interpretation of questions and or use of response scales) and by adherence issues (questionnaire fatigue), there is an ongoing drive for automated monitors providing objective measures collected in a patient-friendly way.

Much effort has concentrated on automated cough detection and cough counting; for reviews see [1,2]. Most of this work is outside the domestic environment where typically performance of cough counters is reported based on standard classification performance metrics and laboratory data bases. The next step to a system with clinical relevance is missing. We suggest that cough counts per se are not relevant. There is a large day-to-day variability in cough of approximately a third [3–6]. Real medical value would only be established once it is validated that the cough detector leads to the correct detection of clinically significant events. In this view, merely demonstrating agreement or correlation between human and automated cough count is far from sufficient.

Here we consider validation of a cough-based alert monitor for COPD exacerbation. In order to attain a patient-friendly monitor, we developed a stationary nighttime cough monitor, equipped with microphone and intended to be placed in the patient's sleeping quarter. It requires no wearables or indeed any other patient action except complying to not turning off the system and, obviously, (regularly) sleeping in designated location. The system is thus characterized as creating an objective outcome, in an unobtrusive, passive manner. Preserving privacy has been a key element of the system from its very start [7,8].

This monitoring system has been reported in [3,9,10] and the current study validates this AE-COPD (acute exacerbation of COPD) alert system in the domestic environment. Here we report the first study which validates

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an automated cough-based system for AE-COPD alert. Additional findings of the study are reported in [6].

2. Methods

2.1. Data collection

To validate an alert mechanism for exacerbations based on cough trend data [3], a prospective longitudinal study of continual cough monitoring in COPD patients was conducted. Forty participants were recruited, monitored using a domiciliary cough monitor, and asked to fill out a daily symptom questionnaire each morning. The study duration was 12 weeks and if no exacerbation occurred in this period, the participant was asked to continue for a further 12 weeks. Monthly visits by the research nurse were scheduled to check the device operation, collect questionnaire data, and fill out the incident report forms. To prevent biased investigation, the study was double blind meaning that processing and interpretation of cough monitor data was completely separated from that of all other data, i.e. the questionnaire data and the COPD exacerbation identification.

The study was reviewed and approved by the Internal Committee Biomedical Experiments of Philips Research and the North East-York Research Ethics Committee, the United Kingdom Health Research Authority (REC Ref.: 21/YH/0203). Informed consent was obtained from all participants involved in the study. Established COPD patients were recruited having had at least 2 exacerbations in the last 12 months. Enrolled patients started the study with a minimum of 4 weeks after an exacerbation. All patients were treated according to the GOLD guidelines. In case of an exacerbation they were asked to contact their GP or community care center. From the 40 enrolled patients, 38 finished the trial with one patient who withdrew almost immediately and the other one changed home leaving equipment behind. The study started August 2022. Various issues, including COVID, data transmission changes affecting equipment, and organizational changes at Philips, delayed the data collection process which finished in June 2024. The Consort diagram of the recruitment process is shown in Figure 1.

2.2. Exacerbation identification and patient questionnaires

Exacerbation identification was patient-initiated with the risk that some exacerbations go unnoticed [11,12]. The start date of a moderate AE-COPD is defined as the date that the participant reports starting steroids and/or antibiotics for their chest or the date that a prescription for steroids and/or antibiotics is issued, excluding renewal of "just-in-case" medications, The end-date of a moderate AE-COPD is defined as the date that the participant reports taking their last dose of steroids and/or antibiotics. The start and end-dates for severe AE-COPD are defined by the start and end dates of treatment (as per moderate AE-COPD) or the duration of hospitalization (whichever is longer).

Participants completed a questionnaire each morning to evaluate respiratory symptoms and medication use [13]. The result is a daily symptom score on a 12-point scale running from 0 to 11. In retrospective analysis, the score is used to raise a questionnaire-based alert if the score rises to 5 or more or to 4 for 2 consecutive days.

A short exit questionnaire was incorporated to ascertain if the presence of the cough monitor put any additional burden on the patient and if the patient would like to have such device in your home in case the system becomes functional (i.e. alert for care giver or patient). Lastly, feedback concerning the trial participation was requested.

2.3. Cough monitor

The deployed cough monitor is a successor to systems used in earlier studies [9,10]. It is a stationary device placed in the sleeping quarters of the participant targeting unobtrusive, privacy-preserving, and passive monitoring of cough. The device holds three main parts: a single board computer (ASUS tinker board 2G) with a USB measurement microphone (Dayton IMM6) and a cellular dongle (Huawei E5330), for a picture of the system see [6]. Audio processing, feature extraction, and cough classifiers were identical to that in earlier trials [9,10,14].

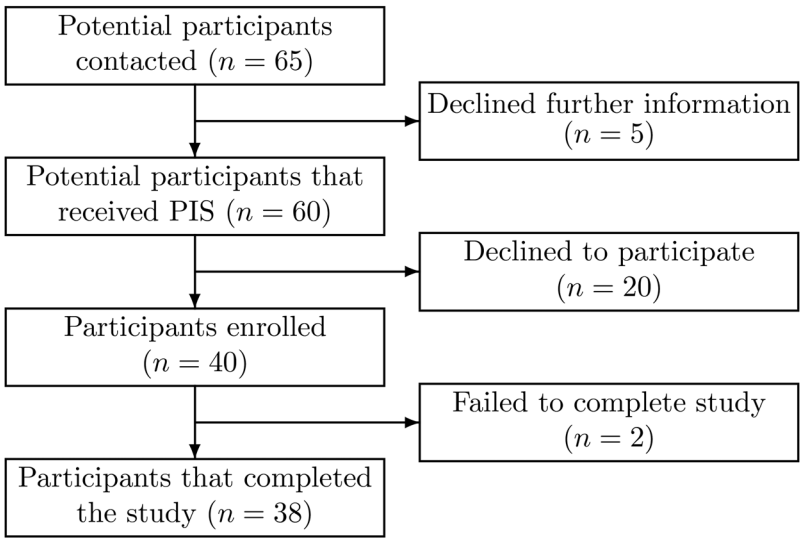

Figure 1. Consort diagram demonstrating participant recruitment and retention. PIS stands for patient information sheet.

Only time stamps and audio features are transmitted at moments where the sound scape changes as privacy-preserving strategy. We refer to sound scape changes as acoustic event where, for a limited number of these events, a one second audio snippet is recorded and transmitted. The availability of short audio excerpts enables creating a personalized classifier and checking for audio issues with the device or its set-up (e.g. a ticking clock next to the monitor can be detrimental).

The system was designed such that it would boot automatically daily to prevent issues with power outage and to safeguard against memory leakage. At installation, it is provided with a start and stop time that were set to 9 pm and 9 am, respectively. Such period is called a session and is assumed to cover the time in bed of all patients. To start and stop monitoring at the correct moments but also to create cough time stamps, timing information is drawn from the cloud. We note that if timing information is not available (e.g. due to connectivity issues), the monitor cannot start a session. The dongle contained an IoT SIM card (TruPhone) operating over the 2G network for the first eight participants. Later participants used a 5G SIM card (Vodafone, UK). After transfer to the cloud, data were downloaded to a proprietary system for analysis.

The protocol follows a free-living approach, i.e. no restrictions imposed by the presence of the monitor. The trial did not track whether the patients were actually at home, sleeping close to the monitor, or their sleep quality.

2.4. Data processing

For each patient, the questionnaires, medical records, and exacerbation periods were collected at Hull, UK. Cough monitor data were processed at Philips, Eindhoven, NL. This section gives a recap of the data processing with more detailed accounts provided in [3,6].

2.4.1. Cough classifier and cough count scale

The cough data processing starts with training a classifier using snippets and features from the first monitoring days as described in [3,14], where solid personalized classifiers were attained when trained with around 200 coughs. The number of days that requires annotation is variable because the number of coughs and acoustic events depends highly on the patient [15]. The median of the classifier performance metrics over the patients are: sensitivity 0.54, specificity 0.99, PPV 0.91, and accuracy 0.95, see [6].

The classifier is applied to all monitored days where we note that for all days the classifier works dominantly on untrained data as audio snippets are only available for a limited number of acoustic events. The final outcome is a time series representing the total number of coughs C observed in a monitoring session (9 pm–9 am). This number of coughs C is mapped to the B-scale by

$$B = \alpha \log(1 + \beta C) \tag{1}$$

with $\alpha = 3.45$ and $\beta = 0.04$. The validated B-scale [6] is constructed such that equidistant steps on the scale reflect equal effects thereby facilitating uniform operation of the processing for patients that have largely different baseline cough counts.

2.4.2. Alert mechanism

To reduce day-to-day variation, the cough count B is smoothed by a causal filter. We then compare how much each observation differs from the baseline level. If for two consecutive days, the smoothed data differs too much from the baseline as defined by a fixed offset, an alert is raised. The time-variant baseline plus offset will be referred to as the dynamic threshold.

The baseline is not a fixed amount but is a time-varying quantity to be able to adapt to aging, seasonal effects, etc. It is determined as the mean value over the past 11 days of a smoothed version of the raw data and with an additional delay of 3 days.

All cough count graphs were inspected and potential issues noted: e.g. graphs starting with a decreasing cough count, alerts being raised at the last monitoring days, and periods of sudden low cough counts (potential patient absence). Following data lock, data was shared between the two sites.

2.4.3. Alert-exacerbation identification

Start days of exacerbations periods were coupled to start days of alert trains. The rule was set as follows: if the alert series start within the exacerbation period or before it with a maximum of 14 days difference, these events are coupled. The number of couplings, the number of alert trains, and exacerbations periods without coupling are counted. Relevant ratios were established to calculate sensitivity, positive predictive value (PPV), and false alert (FA) rate.

Having both exacerbation and objective cough data, the cough count graphs of all periods around exacerbation were visually re-inspected for clues of increased cough (without adapting the alert mechanism). This allows to attain an estimate of the number of exacerbations that do not involve an increased cough count but where other symptoms play a dominant role in the exacerbation.

2.4.4. Daily questionnaire data

The number of questionnaire-based alerts were counted. Correlations between daily questionnaire score (12-points scale) and cough count were calculated for each patient. This was done for the raw cough count C, the mapped cough count B, and the smoothed one.

3. Results

3.1. Patient data

Thirty-eight patients completed the trial. The total duration of the trial was 3981 days and in this period 41 exacerbations (2 severe, 39 moderate) were identified with a report initiated by the patient. On average this amounts to about 1 exacerbation per 100 days agreeing well with the exacerbation frequency noted at the start, see Table 1.

Not all 38 patients had a correctly operating monitor. There were connectivity issues which for 5 patients were so

severe that little to no cough data was available. These patients were excluded from further analysis. For one patient the dominant sound that was observed was a mixture between a throat clearance and a cough [6]. The cough annotation was not adapted to this individuality and therefore data of this patient was set aside. In total, there were 32 patients for which cough annotation was performed on part of the data and typically only in the first monitoring days. From the annotated snippets and the associated features, a personalized cough classifier was developed. The total amount of days with cough count observation was 3110 days. The alert mechanism was operating for 2694 days as for each patient the first 14 days are used to create a baseline.

3.2. Exacerbations and raised alerts

The 32 patients had in total 37 exacerbations. There were 27 exacerbations during operating alert regime (the other ones being in the startup phase or during times the cough monitor did not provide data). From these 27, 11 went without alert (41%), and 16 were coupled to an alert (59%). Examples of the cough counts, alerts, and exacerbation periods are given in Figure 2. Examples of cases with exacerbations reported in the first 14 days are given in Figure 3.

Table 1. Baseline Demographics for Study Participants

Characteristic	All	Male	Female
Patients	38	24	14
Age (years)	72 [57–84]	74.5 [57–83]	71.5 [63–84]
Weight (kg)	79 [44–173]	81 [44–133]	71 [44–109]
Height (cm)	168 [152–198]	172 [160–198]	159 [152–168]
BMI (kg/m^2)	27.7 [16.2–41.3]	27.5 [16.2–41.2]	28.1 [17.3–41.3]
Smoking status			
• Current/ex	7/31	2/22	5/9
• Pack years	46 [10.5–212]	50 [14–212]	37 [10.5–90]
FEV			
• FEV1 (L)	1.13 [0.61–2.81]	1.04 [0.61–2.81]	1.33 [0.98–1.64]
• % Predicted FEV1	43 [20–106]	39 [20–106]	64 [50–79]
CAT score			
• Begin	27 [5–37]	25.5 [13–37]	29.5 [5–37]
• End*	25 [12–36]	23 [15–36]	27 [12–36]
VAS	30 [0.5–85]	31 [0.5–71]	26.5 [3–85]
HARQ	40 [8–70]	29 [9–58]	44 [8–70]
Exacerbations° (1/year)	3 [1–7]	3 [2–6]	5 [1–7]
Admissions° (1/year)	0 [0–2]	0 [0–2]	0 [0–2]

BMI: body mass index; FEV1: forced expiratory volume in 1 s; CAT: COPD assessment test; VAS: visual analogue scale for cough; HARQ: Hull airway reflux questionnaire.
Values are expressed as median and range (in brackets). Not all data reflects the full cohort as indicated by: *($N = 33$) and °($N = 13$).

For the 16 exacerbations coupled to an alert, 7 were early alerts (before the diagnosed onset) and the remaining 9 alerts were generated after the exacerbation onset. In percentages: 44% of alerts were timely and 56% of alerts occurred after exacerbation onset. Calculating back to the total number of exacerbations (27 within the period of operating alert), this means that 26% of the exacerbations led to an early alert based on an objective nighttime cough count.

The cohort of 32 patients was split into three groups according to the median cough count per session and the alerts of the 10 patients with highest count were compared to those with the lowest. The results are in Table 2. Though the number of patients and exacerbations are low, the alert break-down suggest that the early alerts are more effective for the patients with high baseline coughs (chronic coughers).

3.3. Missed exacerbations, false alerts, PPV, and lead time

The second author performed visual inspection on the cough trend data and concluded that from the 11 exacerbations without alert, 3 were with increased cough, and for 8 no appreciable increased cough could be observed. This means that 19 out of the 27 exacerbations (70%) could potentially be identified by cough count; 30% of the exacerbations did not lead to a noticeable increase in cough and are not identifiable by the alert system. An example of an exacerbation without an appreciable increase in cough count is contained in Figure 3.

Next to the alerts coupled to exacerbation, 8 additional alerts were seen and the cough trends were visually inspected. One of these was at the very end of the monitoring period and it is unknown if an exacerbation occurred shortly after. From the remaining 7, 4 surpassed the alert threshold setting where visual inspection showed that the alerts were not part of a prolonged alert sequence. However, three showed a more persistent alert (consistent over time), and may not actually be misclassifications. Examples are shown in Figure 4. In view of the persistent nature of these alerts, it is possible the patients had a Refractory Chronic Cough. However, due to the observational nature of the study this cannot confirmed.

The data allows to make an estimate of the PPV. Since alerts occur as a train of events, we count alert warnings as events rather than occurrences associated with individual days. The PPV count revealed 16 exacerbations (i.e. associated

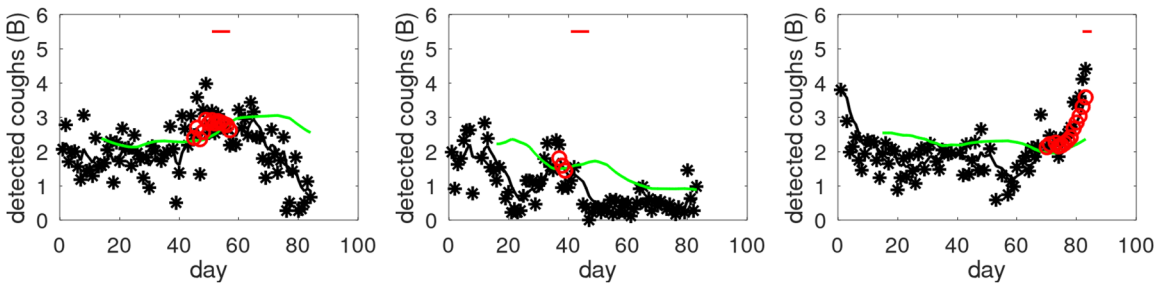

Figure 2. Examples of the cough count (asterisks), smoothed data (black line), dynamic threshold level (green line), raised alerts (red circles), and exacerbation periods (red line pieces at top of graph).

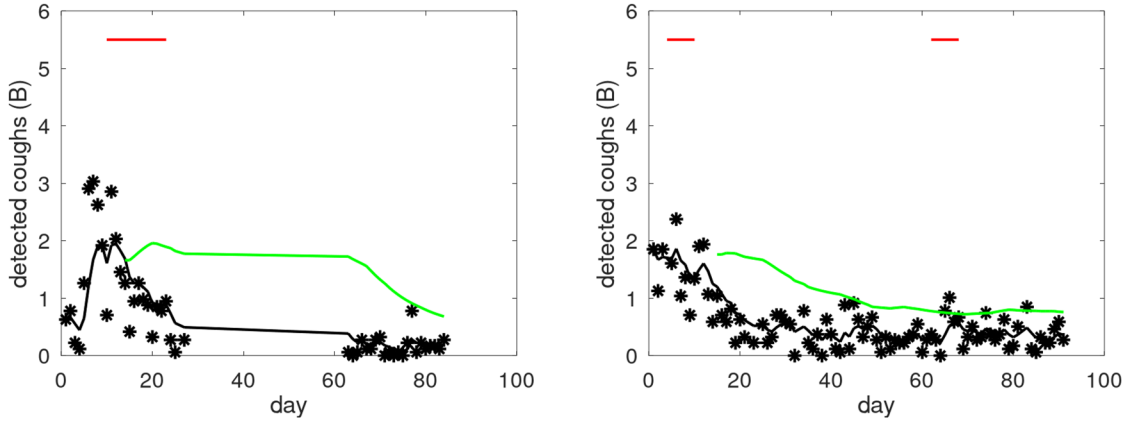

Figure 3. Examples of cases of exacerbations in first 14 days. Cough count (asterisks), smoothed data (black line), dynamic threshold level (green line) and exacerbation periods (red lines). Left plot: cough count graph exhibiting three phases. (i) High cough counts and exacerbation, (ii) missing cough data, and (iii) low stable cough count period without exacerbation. Right plot: cough count plot exhibiting two phases. (i) First 20 days: a decreasing cough count with an exacerbation followed by (ii) stable low cough count. The second exacerbation is not associated with a clearly elevated cough count.

Table 2. Number of Exacerbations and Alerts (Missed and Detected: Subdivided into Early and Late) for the Patients with High and Low Median Cough Counts

Cough (*B*)	Patients	Exacerbations	Alerts			
			Missed	Detected	Early	Late
<0.55	10	9	3	6	1	5
>1.60	10	9	3	6	5	1

with at least one alert) and 8 additional alerts were counted. Ignoring the one alert at the end of the monitoring period, there are 23 alert events. From these 23, 16, or at best 19, are true warnings, giving an PPV estimate of 70–82%.

Lastly, we determined the lead time for the 7 timely alerts. The time between alert and the exacerbation was 4, 5, 6, 6, 8, 9, and 12 days. This means a median of 6 days and a minimum of 4 days.

3.4. Questionnaires

The questionnaire score was processed retrospectively by the questionnaire-alert rules. The total of questionnaire-based alerts was 1244 over 3773 records. The high alert rate is caused by high average scores and makes it impossible to define an association between alerts and exacerbation onsets.

For each patient, cough counts were correlated with questionnaire scores. The median over the patients was 0.07 with quartiles at −0.05 to 0.35 for the raw cough counts with similar results for B-scale and smoothed B-scale counts, see Figure 5. It shows that no correlation is to be expected for a patient: the objective cough count provides different data than the questionnaire data [7].

At the trial closure, participants were asked about their experiences. On the question if the device posed any burden, all answered no with one exception. The one exception was a participant switching regularly from sleeping quarters and taking the monitor along. This is an exceptional case where the participant's profession was at odds with the notion of a stationary and single position system. On the question on if such a system would be attractive to have in the home, 31 replied positively and none negatively. On the question if the system raised any concerns whatsoever, none was reported. As for the trial experience, 25 did not give any explicit reply, 12 patient were positive about the trial where especially the additional contacts with a nurse were mentioned. There was one complaint saying that the lights on the system (indicators for proper functioning of the devices) were too bright.

4. Discussion

The study is limited to COPD patients meaning the cough-based alert mechanism is not validated for other conditions like asthma or viral infections for a more general population. Compared with our earlier study [10] the cohort consisted of less severe COPD patients as evidenced by a lower exacerbation frequency, higher FEV values, and slightly lower CAT. The introduced connectivity is insufficient for productization; not on all trial days data was received, where connectivity issues are the presumed cause, though power disconnection is possible. A limitation of the system is that exacerbations go unnoticed when they are not associated with an increased cough count. Another limitation is the 14 days period that is required to establish a baseline meaning that exacerbations occurring in this period could not be addressed. Since identification of exacerbation was patient-initiated, this may have been triggered partly by the daily questionnaires that the patients were filling out.

It was found that there were 7 extra alerts on a total of 2694 days of potential alerts means one false alert per 385 days. Since some of these 7 alerts may not really be false alerts but missed exacerbations the false alert rate becomes even lower. Following the numbers of the visual inspection as given in Section 3.3, we would arrive at 4 alerts meaning 1 FA per 674 days (i.e. once every 22 months). These FA metrics are extremely low compared to FAs occurring in known questionnaire-based monitoring [10,16].

The questionnaire-based approach for alerting showed poor performance. Adapting the questionnaire-based alert mechanism by two (non-causal) processing steps improves the situation considerably. A new score is created by subtracting the median, using the same alert rules as before,

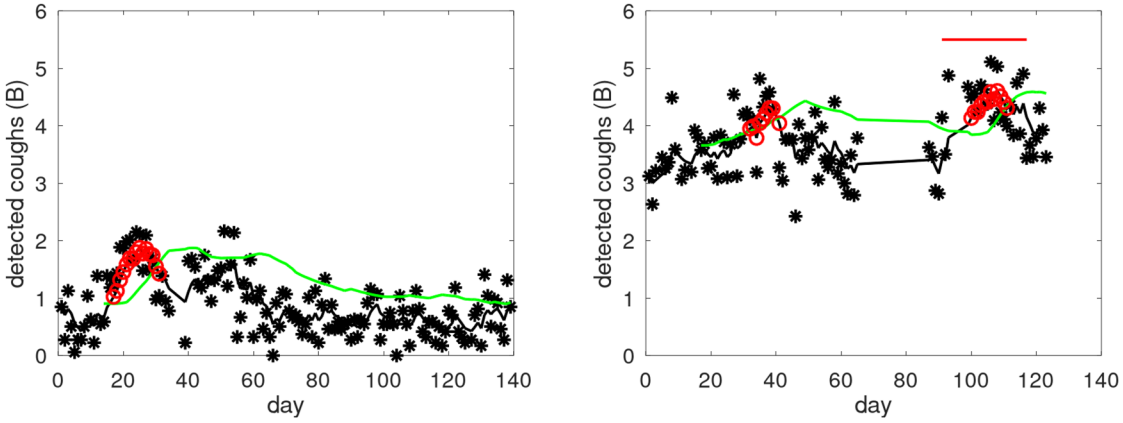

Figure 4. Examples of the alerts being raised consistently over a number of consecutive days due to a rising cough count but without reported exacerbations (or other reported medical event). Cough count (asterisks), smoothed data (black line), dynamic threshold level (green line), raised alerts (red circles) and exacerbation periods (red line pieces at top of graph). Left plot: elevated cough count round day 20–30 with a stable cough count from day 60 onward. Right plot: two alert periods, one with and one without reported exacerbation.

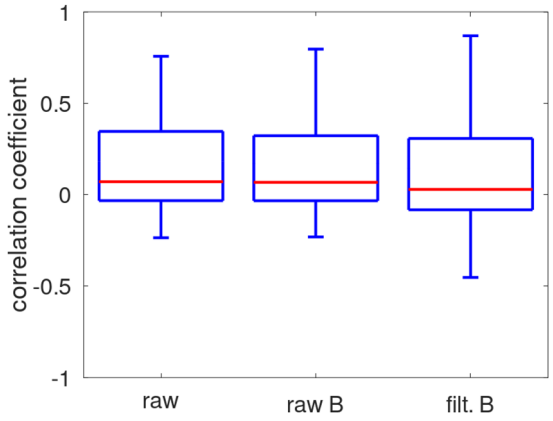

Figure 5. Boxplots of correlation coefficients between questionnaire score and cough counts. Three cough count variants were considered: raw: raw counts; raw B: mapped counts (B-scale); and filt. B: smoothed mapped counts (as shown in cough count graphs).

and creating questionnaire-based alert trains by merging 2 alerts separated by one non-alert day into a single alert event. With this analysis, the daily symptom questionnaire data leads 70% of exacerbations being detected, 35% leading to an early warning with lead time from ranging 4 to 14 days (median 8.5) and a false alert rate of 1 every 90 days and a PPV of 40%.

A 2017 overview paper [17] on prediction models for AE-COPD stated that there is a great variety in the type of predictors, that few were properly validated, and that only one study addressed individual exacerbation risk. Since then, several studies have appeared that are relevant to the current discussion. However, all require active patient participation in one form or another.

In [18] an exacerbation identification system based on vital signs acquired from a pulse oximeter was discussed. The essence is that the distributions of HR, RR, SpO_2 differ among stable and prodromal periods, with an increased average HR and RR and decrease average and less stable SpO_2 in the prodromal periods. Using all three parameters, the obtained AUC for exacerbation identification was close to 0.7.

The automated system called ACCESS [11] acts on 12 symptom-related questions and the measurement of peripheral capillary oxygen saturation (SpO_2), forced expiratory volume in one second (FEV1), and body temperature to generate treatment advice. The system is tuned to high sensitivity, leading to relatively low specificity and a PPV in the order of 10–15% to contact a health care professional.

Recently, a system called COPDPredict [19] was developed and tested. It combines data from patient-reported well-being, forced expiratory volume in one second (FEV1), and C-reactive protein (CRP) levels to provide timely notifications with the FEV1 done every third day and the CRP every 14 days. The performance numbers (sensitivity: 98% and lead time: 7 days [19]) look promising although less than half of the alerts actually correspond to an exacerbation (PPV = 40%). The reported treatment effect looks less promising [20].

In a Korean study [21], medical data (demographic and spirometry data, medications for COPD, and hospital visit for AE) and environmental data (air pollution data and meteorological data, and influenza virus data) were used as inputs to a prediction model. Various AI models were tested, the best resulting in an AUC in the order of 0.75 to predict the risk of exacerbations based on medical claims data but does not predict when they occur. It thus predicts a population rather than an individual model.

The current system differs from the existing ones in various ways. First of all, the intention was not to have the highest sensitivity. Instead, the fundamental notion is the balance the burden/benefit tradeoff for the patient. This is done first of all by using a system that does not require patient input or using a wearable device. Secondly, this is realized by striving for a high PPV. This implies that whenever an alert is raised, it is has a high probability that an exacerbation is imminent or ongoing. Unobtrusiveness and high PPV are basic elements to attain high adherence, which is viewed as crucial for success.

In real life, the system has to operate in an uncontrolled setting. This was clearly the case in this trial set-up: there were periods of missing cough data and it was not tracked if the patient was actually at home and in the sleeping

quarters during the monitoring hours. No separate mechanism for absence identification was used or built, no immediate actions were undertaken if the system was down. The system appears sufficiently robust to be able to operate under real-life conditions.

5. Conclusions

We have validated the performance of a cough-based alert system for COPD exacerbation in a double-blind trial. The system is a stationary monitor in the bedroom passively monitoring the patient's cough during sleeping hours. From the data, it is estimated that around 30% of the exacerbations did not give rise to an increase in cough. Though based on a single observation, the alert mechanism flagged 59% of the exacerbations. For the cases with alerts preceding the onset, the associated lead time was 4 days or more.

Disclosure statement

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Data availability statement

All requests can be made to the corresponding author.

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