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With healthcare objectives and budget constraint, remote monitoring of chronic obstructive pulmonary disease (COPD) patients is an important challenge in most European countries.[1] Recent works have shown that it is possible to predict COPD exacerbation based on monitoring of simple parameters, such as the respiratory rate (RR) of the patient in spontaneous ventilation [2-4] or under non-invasive ventilation [5]. Until now, these devices do not allow a daily automatic data remote transmission,[4] or it is restricted to patients under mechanical ventilation [5].

TeleOx® (SRETT, Boulogne-Billancourt, France), the first oxygen flow rate remote monitoring device, also allows a RR measurement by associating a pressure sensor and a fluidic oscillator flow sensor. A median RR is output every 5 minutes based on time interval between two consecutive respiratory cycles.

In this study, we compared the corresponding RR measurements between TeleOx® and the reference polygraph (Nox-T3®, Nox Medical Inc. Reykjavik, Iceland) from COPD patients under nasal oxygen therapy with flow rates between 0.5 and 5.0 litres per minute. Patients without mechanical ventilation and without any other respiratory pathology were eligible to the study if they would undergo a ventilatory polygraph record for other reasons.

This study was approved by our institutional board (CEPRO n° 2016-005).

Result agreement was estimated using the Bland-Altman method, presented here, and the Passing-Bablok regression method, for non-parametric regression analysis, presented in the online supplement.

In order to obtain an error margin of 3% and a confidence interval of 95%, 1000 valid measurement points were necessary, which demands 14 patients' recordings of about 6 hours each.

Results are presented as mean ± standard deviation.

Several software versions were necessary to improve its reliability. The first version of TeleOx® was used to record 8 patients, the second version 12 and the third version 14 patients with respectively 38%, 33% and 93% of success rate. Here, we analyse results from the last version.

From the fourteen patients included, 1099 valid measurement points allowed statistical analysis. Included patients exhibit a forced expiratory volume in one second (FEV1) of 1032 ± 619 ml (or 44 ± 23 % of predicted value), a PaO2 in spontaneous ventilation and ambient air at 65.3 ± 6.9 mmHg, a PaCO2 at 43.8 ± 5.1 mmHg. 21 % of the population was classified GOLD B, 64% GOLD D, 7% GOLD A and 7% GOLD C. Anthropometric data can be found in the online supplement.

The RR measures from the polygraph were 19.45 ± 5.39 breaths per minute and from the TeleOx® were 19.41 ± 5.38 breaths per minute.

The bias calculated by Bland-Altman method is 0.046 within [-3.865, 3.957] limits of agreement at 95% (figure 1).

No participant found TeleOx® intrusive.

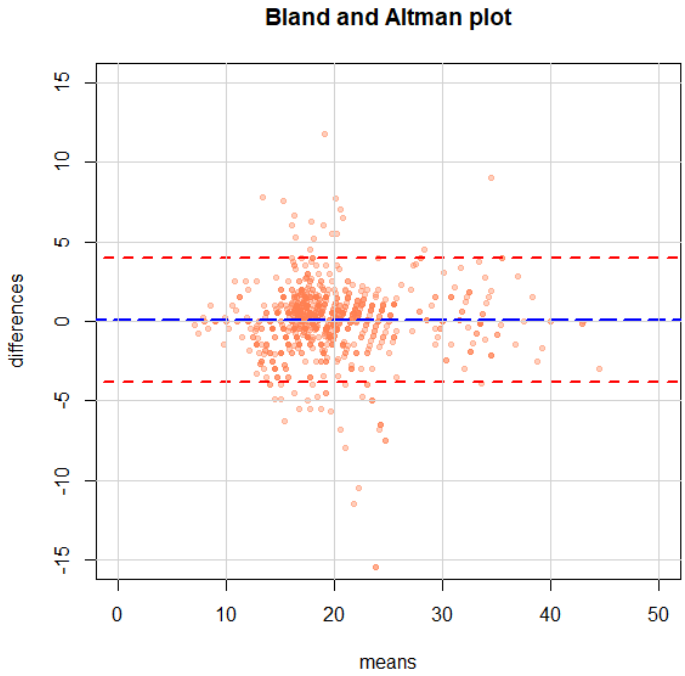

Figure 1:

Comparison using Bland-Altman method of respiratory rate (RR) measurements by TeleOx® and Nox-T3 on a set of 1099 valid measurement points. Bias is presented by a dashed blue line and upper and lower 95% limits of agreement of the differences are presented by dashed red lines.

A recent study on RR remote monitoring devices shows a measure quality discrepancy, with measurement bias of 3.01 and -3.21 cycles/minute (corresponding limits of agreement are -11.17 to 17.19 and -12.71 to 6.30) for measurement methods based on photoplethysmography and on camera respectively.[6] Compared to these devices, the measurement bias of TeleOx® is far smaller and its limits of agreement interval is narrower. This device is also less intrusive and thus may improve patient adhesion to remote monitoring.

Important RR measurement differences are found to happen in periods where artefacts (as apnoea, hypopnoea and mouth breathing) take place, which makes median RR more difficult to measure to both devices, or during the transition zone (first minutes of the recording when TeleOx® is calibrating).

No analysis considering each patient separately is presented because most of the patients present a narrow range of RR values combined with a small sample size, interfering method comparison. Moreover, we considered the addition of more patients unnecessary, since we have the aimed sample size of RR measurements covering a large range of RR values.

As it has been shown with VisionOx®, another tool described in 2012 (finally not developed as such because it was not communicating), more and more evidence suggests that an increase in RR is predictive of an exacerbation.[4] In addition, a recent study demonstrated the benefit of monitoring RR by photoplethysmography using a pulse oximeter in the COPD patient homes. [7] Such monitoring is, however, dependent on the patient's compliance.

To the best of our knowledge, TeleOx is the first near real-time RR remote monitoring tool for COPD patient under oxygen therapy without mechanical ventilation. This wireless connected device is non-invasive and simple to use, allowing for remote monitoring of treatment compliance, oxygen flow rate and now the RR of the patient. These features make it an excellent tool for LTOT patient remote monitoring.

The next step of our work is to test the ability to capture changes in RR of the patients during stable state, acute exacerbation and recovery. Future development will need to address the detection of small changes in breathing rate patterns in the context of a

complex background.

Declarations:

Ethics approval and informed consent:

This study was approved by our institutional board (CEPRO n° 2016-005), Consent to participate was obtained

Consent for publication:

All the authors agreed to this publication

Data availability:

In supplementary material

Funding:

No funding was received

Conflict of interest:

X. L. Le and D. P. Q Nguyen are employed by SRETT.

J. Alves Pegoraro is member of the project PHD CIFRE from the French government and her salary is paid by SRETT.

No conflict of interest, financial or other, exists for the authors.

The abstract of this paper was presented at the British Thoracic Society Winter Meeting 2017 as a poster presentation with interim findings. The poster's abstract was published in "Poster Abstracts" in Thorax: http://dx.doi.org/10.1136/thoraxjnl-2017-210983.208

Authors' contributions:

J.G-B, X.L.L, J.S, R.A, A.G, L.G: conception, hypothesis delineation and design of the

study. J.G-B, J.S, X.L.L, D.P.Q.N, L.G, A.G, J.A.P: Acquisition of data or analysis and interpretation. J.G-B, J.S, X.L.L, D.P.Q.N, L.G, R.N, A.G, J.A.P: Writing the article and correction

Acknowledgements:

We thank Pr Thomas Similowski (Groupe Hospitalier Pitié-Salpetrière Charles Foix, Service de Pneumologie et Réanimation Médicale, Paris) for advice on statistical analysis. In addition, we thank the paramedic staff of "R3S" department for the data collection.

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