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Comparison of ventilator-integrated end-tidal CO_2 and transcutaneous CO_2 monitoring in home-ventilated neuromuscular patients

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ABSTRACT

Background: Non-invasive transcutaneous capnometry ($TcCO_2$) is used to assess the home ventilation's efficiency. Recently, end-tidal CO_2 ($ETCO_2$) sensors have been integrated in life-support home ventilators. The purpose of this study was to compare the ventilator-integrated $ETCO_2$ with $TcCO_2$, in home-ventilated neuromuscular disease patients.

Methods: $ETCO_2$ and $TcCO_2$ were simultaneously measured during one night in 28 patients. Daytime blood gases were drawn on the following morning to measure arterial PCO_2 ($PaCO_2$).

Results: Compared to $PaCO_2$ values, both $ETCO_2$ and $TcCO_2$ showed a small bias (−0.1 mmHg and 0.6 mmHg, respectively) and a similar critical difference (6.8 mmHg and 7.3 mmHg, respectively). We found a good correlation between $ETCO_2$ and $TcCO_2$, both considering the mean nocturnal PCO_2 ($r = 0.897$, $p < 0.001$; bias −1.1 [− 9.0; 6.9] mmHg) and the maximal PCO_2 value over the night ($r = 0.905$, $p < 0.001$; bias 3.1 [−4.5; 10.8] mmHg). The concordance of the two techniques in detecting overnight PCO_2 fluctuations was high, with $r = 0.919$ ($p < 0.001$) for the time spent with PCO_2 >45 mmHg and $r = 0.943$ ($p < 0.001$) for the time with PCO_2 >50 mmHg.

Conclusions: The ventilator-integrated end-tidal CO_2 monitoring is as reliable as the currently used transcutaneous measurement, resulting to be a valuable proxy of the overnight PCO_2 evolution. This result opens the possibility of a simplification in the monitoring of home ventilated patients, since $ETCO_2$ measurement can be performed directly at home, with a low additional cost. However, the accuracy of both these measurement techniques is not sufficient to replace blood gases, which remain the reference examination.

ClinicalTrials.gov registration: NCT02068911.

1. Introduction

The development of a restrictive respiratory failure represents one of the leading causes of morbidity and mortality in neuromuscular disease (NMD) patients [1–5]. Its management by long term home mechanical ventilation (HMV) is currently one of the few available treatments improving the clinical course of these patients [3–8].

Monitoring of the ventilation's efficiency requires regular assessment of the partial pressure of carbon dioxide (PCO_2) to confirm the correction of alveolar hypoventilation [9,10]. The reference technique is PCO_2 measurement in blood gases obtained by arterial puncture [9–11], but it has some limitations, being an invasive method which may disrupt sleep, and reflecting only a snap shot of the variable alveolar ventilation during sleep [12–14]. In recent years, two non-invasive continuous PCO_2 monitoring tools were developed allowing the assessment of arterial PCO_2 either with a transcutaneous sensor (transcutaneous capnometry,

Abbreviations: AASM, American Academy of Sleep Medicine; BMI, body mass index; $ETCO_2$, end-tidal CO_2; HMV, home mechanical ventilation; MEP, maximal expiratory pressure; MIP, maximal inspiratory pressure; NMD, neuromuscular diseases; $PaCO_2$, arterial partial pressure of CO_2; PaO_2, arterial oxygen partial pressure; $TcCO_2$, transcutaneous measure of CO_2; VC, vital capacity.

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$TcCO_2$) or the analysis of exhaled gases (end-tidal CO_2, $ETCO_2$) [12–14]. $TcCO_2$ has been progressively used for monitoring the follow-up of long-term ventilated patients, relying on a small number of studies of its performance during HMV [9]. Conversely, $ETCO_2$ was largely adopted to monitor patients during anaesthesia, but it is considered to be less suitable for HMV monitoring, being imprecise in the presence of parenchymal lung diseases and in case of intentional or unintentional air leaks, which regularly occur during HMV [9,15,16]. This technique may however represent an interesting option in ventilated NMD patients, as they mostly have an intact lung parenchyma and they are often ventilated using a non-vented respiratory circuit.

Recently, $ETCO_2$ sensors have been integrated in life-support home ventilators, offering the possibility to monitor $ETCO_2$ and air leakage simultaneously, and thus allowing to adjust for this important source of error. The development of ventilator-integrated $ETCO_2$ monitoring opens the possibility to assess the ventilation's efficacy directly and repeated at home with a low additional cost, allowing a simplification in the management of HMV.

The purpose of this study was to compare the measure of the PCO_2 obtained by a ventilator-integrated $ETCO_2$ monitor, with the one obtained by $TcCO_2$, in home-ventilated NMD patients.

2. Materials and methods

2.1. Patients and experimental set-up

Adult patients with neuromuscular disease treated with home invasive or non-invasive ventilation were recruited during a routine follow-up hospitalization at the Home Mechanical Ventilation Unit of the Raymond Poincare University Hospital, Garches, France. Long-term oxygen therapy and unplanned hospitalization for acute respiratory events were considered as exclusion criteria.

According to routine clinical practice in the unit, a transcutaneous capno-oxymetry was performed, and daytime blood gas values were obtained on the following morning. Blood samples were drawn at rest and immediately carried in an ice bag to the central hospital laboratory for analysis.

For the night of the study, the patient's home ventilator was replaced by the study ventilator with $ETCO_2$ monitoring capability (VIVO 50 or VIVO 60, BREAS Medical, Mölnlycke, Sweden) and an unvented ventilator circuit. The patient's usual ventilatory mode and settings were maintained. Both $TcCO_2$ and $ETCO_2$ were simultaneously recorded in each patient during the same night.

The study was conducted in accordance with the declaration of Helsinki and was approved by the local ethical committee (Comité de Protection des Personnes Ile de France XI; approval N. 2013-AO1629-36); written informed consent was obtained from all patients. ClinicalTrials.gov registration number: NCT02068911.

2.2. End-tidal CO_2

The end-tidal CO_2 ($ETCO_2$) was measured on the gas expired by the patient using infrared spectrophotometry with mainstream sensor (IRMA $ETCO_2$, Phasein AB, Stockholm, Sweden) and recorded with a sampling rate of 10 Hz by a dedicated module, integrated in the study ventilators. The sensor required no calibration. An algorithm analysed the capnography curve on a breath-to-breath basis, to detect the presence of an $ETCO_2$ plateau, reflecting the alveolar CO_2 concentration during a breathing cycle; ventilator's air leakage was estimated on a breath-to-breath basis, as the difference between the volume delivered by the ventilator and the volume expired by the patient, and used to filter out all $ETCO_2$ values for which leakage was >5%.

2.3. Capno-oxymetry

Overnight continuous $TcCO_2$ and oxygen saturation (SpO_2) were recorded using a Digital Monitoring System (SenTec, Therwil, Switzerland) equipped with a combined Severinghaus-type $TcCO_2$ electrode and SpO_2 sensor (V-Sign, SenTec, Therwil, Switzerland). As recommended by the manufacturer, the electrode was calibrated in the integrated docking station before and after each measurement, using a service gas (mixture of 8% CO_2, 12% O_2, and 80% N_2), allowing the measured $TcCO_2$ values to be corrected for calibration drift. The electrode temperature was set at 42 °C to increase blood flow, thereby improving skin permeability to gases and arterializing the capillary blood. An integrated factory algorithm estimated the arterial PCO_2 from the measured PCO_2, accounting for temperature and metabolic correction factors. According to the manufacturer, the measurement resolution for $TcCO_2$ was 0.1 mm Hg, the in vitro drift <1%/hour and the response time <80 s. The $TcCO_2$ signal sample interval was set at 4 s. All studies were visually inspected by the same investigator (AO) to exclude periods with artifacts from the results.

2.4. Statistical analysis

Statistical analysis was conducted using R 3.1.2 statistical software (R Core Team 2014, GNU General Public License). Continuous variables were described by mean and standard deviation; percentages were used to describe dichotomous or categorical variables. The $ETCO_2$ and $TcCO_2$ values measured in the morning at the time of the blood gazes were first compared to the concomitant $PaCO_2$ values. Subsequently, the $ETCO_2$ and $TcCO_2$ measurements of each patient were corrected for the difference to $PaCO_2$ prior to the comparison of the two techniques.

The correlation between corresponding measurements was evaluated by computing the Pearson correlation coefficient and their agreement using the Bland-and-Altman method, computing bias (with 95% confidence interval) and limits of agreement. The critical difference (a marker of precision) was assessed based on the [bias - SD; bias + SD] interval, where SD was the standard deviation of the distribution of the differences. A sample size of 28 was chosen as it allowed to estimate the 95% confidence interval of the bias with a precision of 2 mmHg, which was considered as the minimal clinically significant difference.

3. Results

28 patients were included in the study. In one out of the 28 included patients, the $ETCO_2$ recording was not exploitable because of a technical problem, and in a different patient we obtained no $TcCO_2$ recording.

24 patients (86%) were ventilated non-invasively (using nasal interface in 21 and naso-buccal in 3) and 4 were ventilated through uncuffed tracheostomy. A volumetric ventilatory mode was used in 43% of the patients, including all 4 patients with tracheostomy.

The patients presented 14 different neuromuscular diseases, the most frequent being Duchenne or Becker muscular dystrophy ($N = 10$), myotonic dystrophy type 1 (Steinert's disease, $N = 6$), congenital muscular dystrophies ($N = 3$) and sarcoglycanopathies ($N = 2$). The characteristics of the study population are detailed in Table 1.

3.1. $ETCO_2$ and $TcCO_2$ vs blood gazes

The PCO_2 values obtained in the morning by $ETCO_2$ showed a good correlation ($r = 0.867$, $p < 0.001$) with the values obtained by simultaneous blood gazes. There was almost no difference between

Table 1
Characteristics of the study population.

Characteristic	Mean (SD) or N (%)
Women (N, %)	8 (29%)
Age (y)	37.6 (12.6)
Weight (kg)	66.2 (28.4)
BMI (kg/m^2)	23.6 (10.0)
Respiratory parameters	
VC sitting (%pred)	30 (23)
MIP (cmH_2O)	26 (17)
SNIP (cmH_2O)	28 (14)
MEP (cmH_2O)	26 (18)
Morning blood gases	
pH	7.39 (0.03)
$PaCO_2$ (mmHg)	43.4 (6.7)
PaO_2 (mmHg)	77.3 (30.8)
Total CO_2 (mmol/l)	27.4 (3.9)
Ventilation	
Volumetric mode (N, %)	12 (43%)
Interface (N, %)	
Tracheostomy	4 (14%)
Nasal	21 (75%)
Naso-buccal	3 (11%)
HMV duration (y)	7.5 (5.8)
Nocturnal Oximetry	
Duration of the recording (min)	546 (124)
Mean Oxygen Saturation (%)	95.1 (3.0)
Time with SpO_2 <90% (%)	4.8 (13.2)

BMI: body mass index; VC: vital capacity; %pred: percentage of the predicted value; MIP: maximal inspiratory pressure; MEP: maximal expiratory pressure; $PaCO_2$: arterial partial pressure of CO_2; PaO_2: arterial partial pressure of O_2; $TcCO_2$: transcutaneous measure of CO_2; HMV: home mechanical ventilation.

the two values (bias −0.1 mmHg [95%CI −1.6; 1.4]), and the critical difference was 6.8 mmHg (Fig. 1). The results were similar comparing the values obtained by $TcCO_2$ with those obtained by simultaneous blood gazes (r = 0.840, p < 0.001; bias 0.6 mmHg [95%CI −0.9; 2.1], critical difference 7.3 mmHg) (Fig. 2).

3.2. *$ETCO_2$ vs $TcCO_2$*

The results of both $ETCO_2$ and $TcCO_2$ displayed in a profile graph of the study night allowed a visual evaluation of the overall trend (Fig. 3). In accordance with the technical differences between the two methods, $ETCO_2$ values were not available during periods of prolonged interface leakage, which accounted for a mean of 6% of the recordings in our population (range 0%–31%), whilst $TcCO_2$ values were available even during these periods, being limited in their interpretation only by artifacts, which represented in mean 1% of the recording time (range 0%–4%).

We found a good correlation between $ETCO_2$ and $TcCO_2$ both considering the mean and the maximal PCO_2 value over the night (r = 0.897, p < 0.001 and r = 0.905, p < 0.001, respectively). The Bland and Altman analysis showed a difference between $ETCO_2$ and $TcCO_2$ of −1.1 mmHg [95%CI −2.8; 0.6] for the nocturnal mean value (limits of agreement − 9.0 to 6.9 mmHg), and 3.1 mmHg [95%CI 1.6; 4.7] for the maximal value (limits of agreement −4.5–10.8 mmHg) (Figs. 4 and 5). The concordance of the two techniques in detecting overnight PCO_2 fluctuations was high, with an r = 0.919 (p < 0.001) for the time spent with PCO_2 >45 mmHg and r = 0.943 (p < 0.001) for the time with PCO_2 >50 mmHg (Fig. 6).

4. Discussion

Our data show that ventilator-integrated End-Tidal CO_2 monitoring represents a valuable alternative to transcutaneous PCO_2 recording for the monitoring of home-ventilated patients with neuromuscular diseases. The results obtained with the two techniques were well correlated and showed a good accuracy and a small bias. Furthermore, both techniques showed a similar accuracy when compared with arterial PCO_2 assessment.

$TcCO_2$ has been increasingly used for follow-up monitoring of home ventilated patients, allowing to detect episodes of transient hypoventilation, that are not detected by punctual blood gazes [9]. Contrary to older devices, which showed a poor agreement with arterial PCO_2 because of a calibration drift occurring during extended recording times [17], the $TcCO_2$ monitor used in our study (SenTec Digital Monitoring System) was calibrated at the beginning and at the end of the recording period, allowing the measured $TcCO_2$ values to be corrected for calibration drift. As a consequence, we found a very small bias between the $TcCO_2$ value in the morning and the PCO_2 value obtained by concomitant arterial blood gases. Our results are in accordance with two recent studies performed with the same device, showing a bias of 0.8 mmHg and a limit of agreement of −4.9 to 6.5 in the first [12] and a bias of −0.8 mmHg and a critical difference of ±6.8 mmHg in the second [14]. However, the use of this monitoring tool is limited in the outpatient setting as it is quite expensive and fragile.

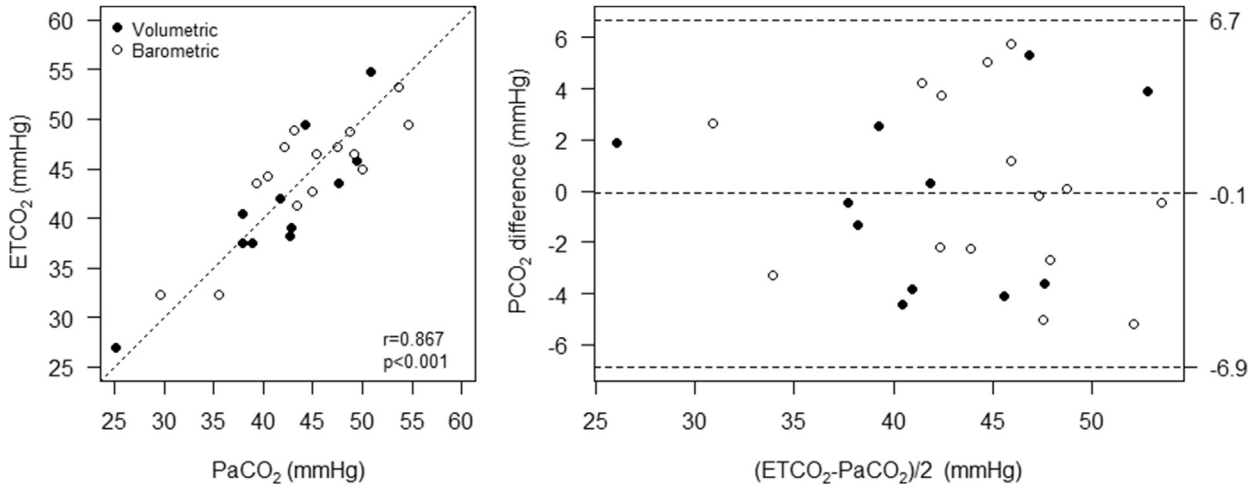

Fig. 1. Comparison of the PCO_2 obtained in the morning by $ETCO_2$ and blood gazes. $ETCO_2$: end-tidal CO_2; $PaCO_2$: arterial partial pressure of CO_2. On the right panel, dotted lines represent bias and limits of agreement.

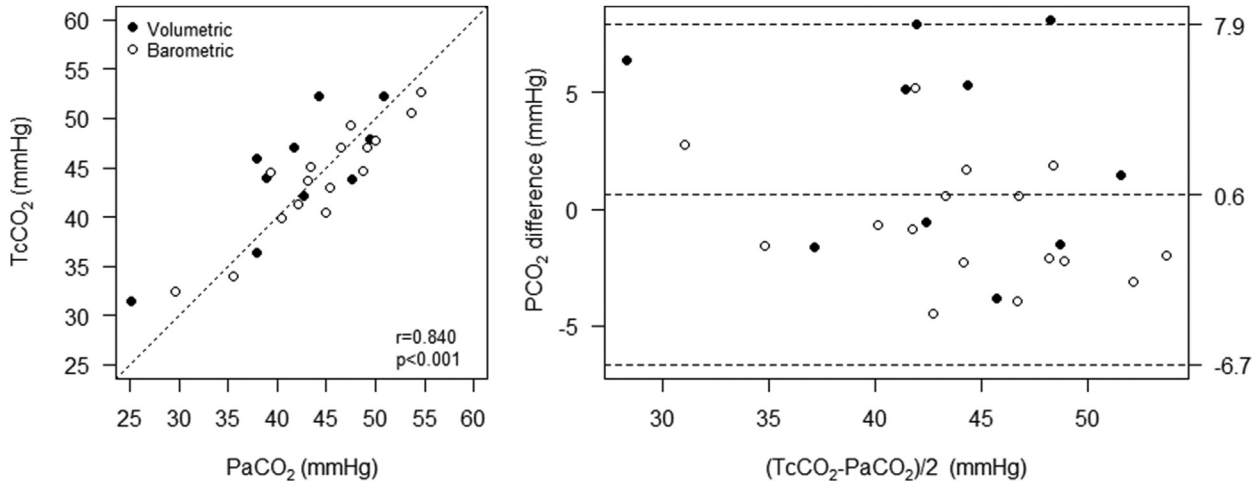

Fig. 2. Comparison of the PCO_2 obtained in the morning by $TcCO_2$ and blood gazes. $TcCO_2$: transcutaneous measure of CO_2; $PaCO_2$: arterial partial pressure of CO_2. On the right panel, dotted lines represent bias and limits of agreement.

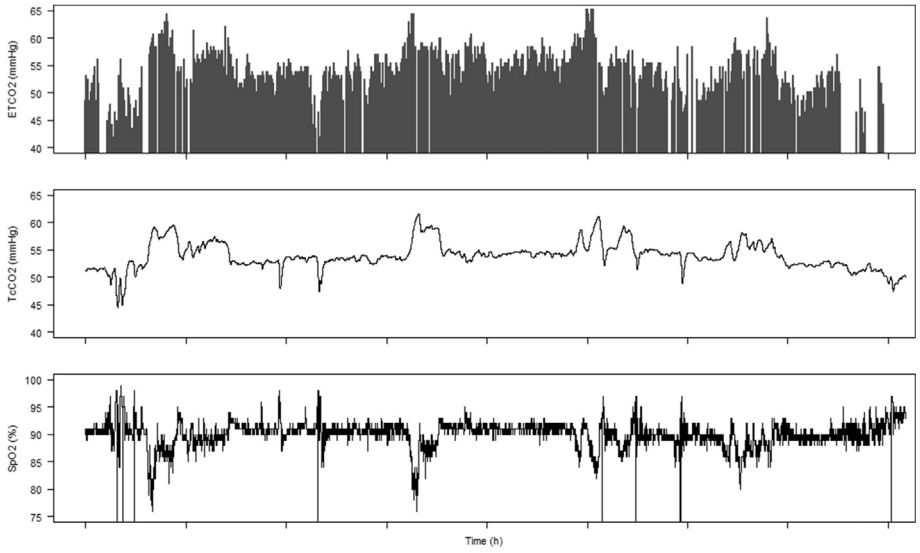

Fig. 3. Profile graph of $ETCO_2$ and transcutaneous capno-oximetry recording of a single patient. $ETCO_2$: end-tidal CO_2; $TcCO_2$: transcutaneous measure of CO_2; SpO_2: transcutaneous oxygen saturation.

In our study the ventilator-integrated $ETCO_2$ module showed a similar accuracy as $TcCO_2$, when compared with arterial PCO_2 assessment, allowing to consider it as a valid measurement according to the American Academy of Sleep Medicine (AASM) guidelines [9]. The advantage of the ventilator-integrated $ETCO_2$ monitor lies in the low additional cost and in its continuous availability at the patient's home. In previous studies, $ETCO_2$ was found to be unsuitable for the monitoring of mechanical ventilation [18–20]. These results were influenced by some of the characteristics of $ETCO_2$, specifically its inaccuracy in the presence of ventilation/perfusion inhomogeneity (depending on the presence of parenchymal lung diseases) and in case of exhaled sample dilution due to intentional or unintentional air leaks, which regularly occur in ventilated patients [9,15,16]. The first source of error is dependent of the clinical setting, and was not present in our population, since neuromuscular disease patients mostly have an intact lung parenchyma in contrast to COPD and intensive care units patients, the subjects of most of the previous studies. However, the main novelty of our protocol was the filtering of the $ETCO_2$ values according to the instantaneous leakage measurement, since both values were recorded by the ventilator. Despite the missing information about PCO_2 during the periods of prolonged leak, the results provided by the $ETCO_2$ monitoring were equivalent to those obtained by $TcCO_2$. We found no statistically significant correlation between magnitude of leaks and inaccuracy of $ETCO_2$, even though the four patients having >10% leaks were amongst the participants showing the largest differences between $ETCO_2$ and $TcCO_2$. Interestingly, we found no apparent difference in the accuracy of $ETCO_2$ between patients ventilated with barometric and volumetric mode, despite the differences in the expected dilution effect in case of leaks between the two modes. On the other hand, the ventilator-integrated $ETCO_2$ monitoring gave informations about prolonged leakage during the study night, which represent one of the main problems leading to ventilation's inefficacy, but were not available with TcCO2.

The main limitation of our study is represented by the selection

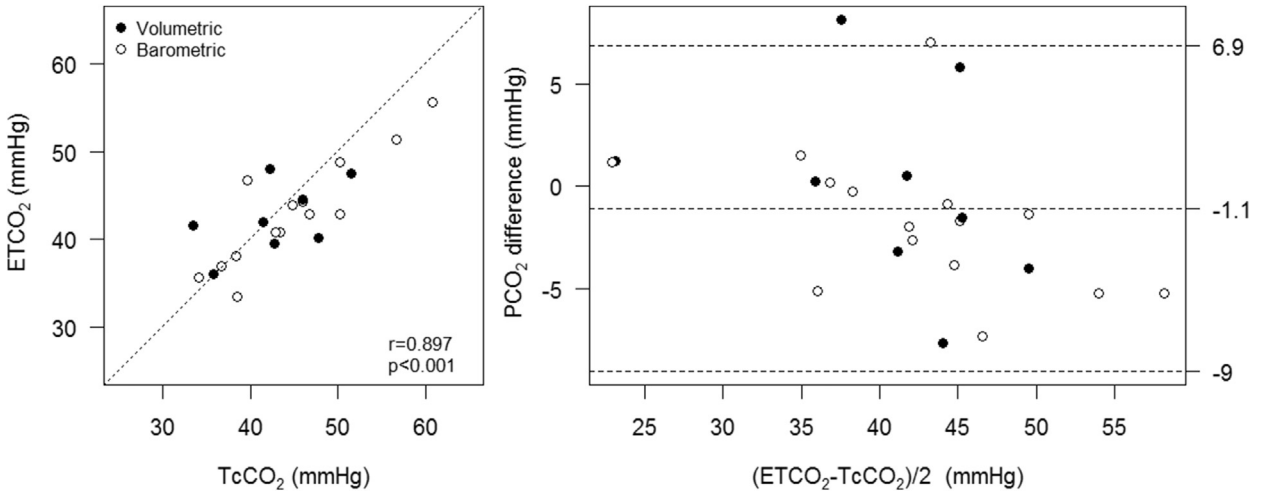

Fig. 4. Comparison of the mean nocturnal PCO_2 obtained by $ETCO_2$ and $TcCO_2$. $ETCO_2$: end-tidal CO_2; $TcCO_2$: transcutaneous measure of CO_2. On the right panel, dotted lines represent bias and limits of agreement.

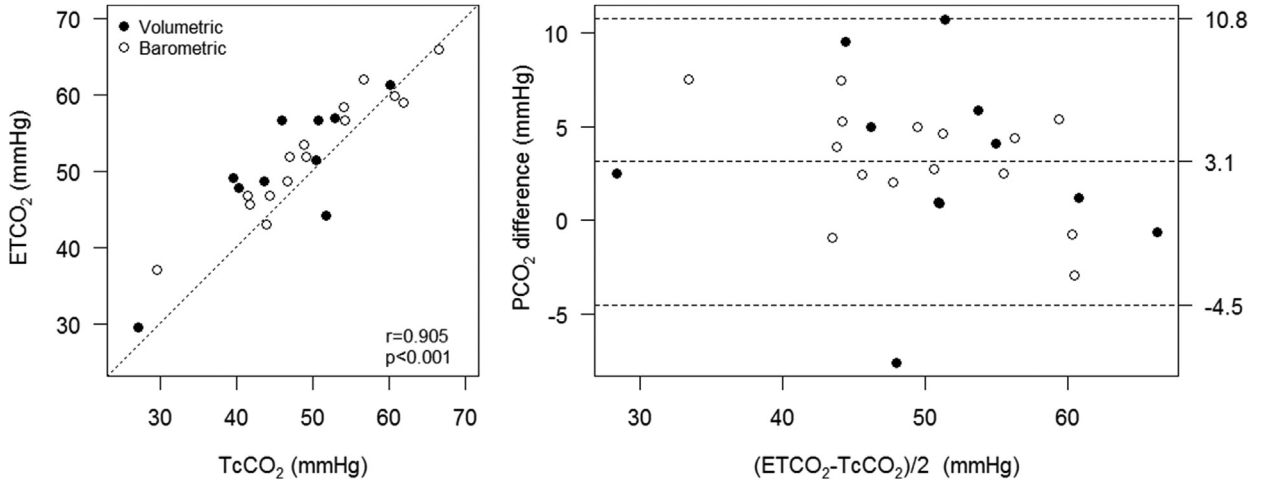

Fig. 5. Comparison of the maximal nocturnal PCO_2 obtained by $ETCO_2$ and TcCO2. ETCO2: end-tidal CO_2; $TcCO_2$: transcutaneous measure of CO_2. On the right panel, dotted lines represent bias and limits of agreement.

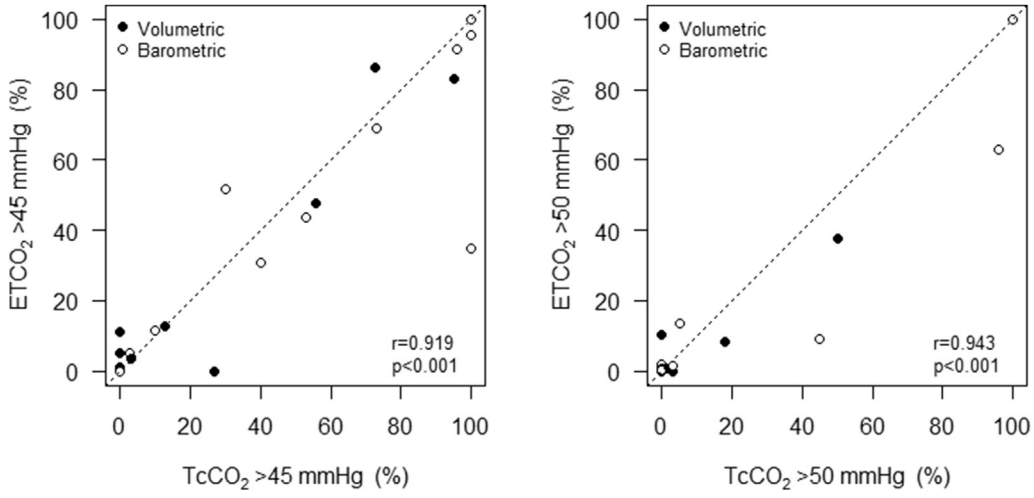

Fig. 6. Time spent with PCO_2 >45 and > 50 mmHg according to $ETCO_2$ and $TcCO_2$. $ETCO_2$: end-tidal CO_2; $TcCO_2$: transcutaneous measure of CO_2. Comparison of ventilator-integrated End-Tidal CO_2 and transcutaneous CO_2 monitoring in home-ventilated neuromuscular patients.

of a population without expected airways and lung parenchyma abnormalities, not allowing the extension of our results to other populations and settings. It should however be noted, that only the absolute PCO_2 values and not their relative overnight variations would be affected by lung parenchyma abnormalities, when the ventilation/perfusion distribution remain stable over the assessment period. As a consequence, $ETCO_2$ may be reliable in this setting, after correction of the absolute PCO_2 value for the difference with arterial PCO2. Furthermore, the measurement of $ETCO_2$ and the leak estimation require the use of an unvented ventilation circuit, which is usually the case when life-support ventilators are prescribed [21]. Some further limitations of the study arise from the inhomogeneous of patients population according to ventilator mode and interface, the hospital setting and the use of a ventilator different from the usual patient's one.

Despite the good correlation and the small bias when compared to arterial PCO_2, none of the tested non-invasive methods of PCO_2 measurement can completely substitute the gold standard blood gazes, since they both showed a similar and quite poor precision in the estimation of absolute $PaCO_2$, with a critical difference near to 7 mmHg. Nevertheless, both transcutaneous and end-tidal analyses of gas exchange seem to be appropriate surrogates for $PaCO_2$ for the overnight monitoring of the PCO_2 variations.

5. Conclusions

The ventilator-integrated End-Tidal CO_2 monitoring is as reliable as the transcutaneous measurement, resulting to be a valuable proxy of the overnight PCO_2 evolution in ventilated neuromuscular patients. This result opens the possibility of a simplification in the monitoring of HMV, since $ETCO_2$ measurement can be performed directly and repeated at home, with a low additional cost. However, the accuracy of both these measurement techniques is not sufficient to replace blood gases, which remains the reference examination to determine absolute PCO_2 value.

Author contributions

DO, IV, DA and AO: designed the experiment; DO, HP, XA, SP and AO: conducted the research; DO, IV, FL and AO: analysed the data and performed the statistical analyses; DO, HP, FL and AO: wrote the manuscript; AO has primary responsibility for the integrity of the data and the accuracy of the data analysis. All authors had full access to all of the data (including statistical reports and tables) in the study, revised the manuscript for important intellectual content and approved the final version of the manuscript.

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Pr. D. Orlikowski, X. Ambrosi, I. Vaugier, S. Pottier, Pr. D. Annane and A. Ogna declare that they have no conflict of interest. Pr. F. Lofaso and H. Prigent have no conflict of interest related to the present work to disclose; the Service de Physiologie-Explorations Fonctionnelles of Garches received research funds from ResMed France, not related to the present work.

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Summary of conflict of interest statement

Pr. D. Orlikowski, X. Ambrosi, I. Vaugier, S. Pottier, Pr. D. Annane and A. Ogna declare that they have no conflict of interest. Pr. F. Lofaso and H. Prigent have no conflict of interest related to the present work to disclose; the Service de Physiologie-Explorations Fonctionnelles of Garches received research funds from ResMed France, not related to the present work.

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