Monitoring Carbon Dioxide Tension and Arterial Oxygen Saturation by a Single Earlobe Sensor in Patients With Critical Illness or Sleep Apnea*

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Objectives: The purpose of the study was to evaluate a novel, combined sensor for transcutaneous monitoring of arterial oxygen saturation and carbon dioxide tension.

Design: The new monitoring technique was compared to established reference methods.

Setting: ICU and sleep laboratory of a university hospital.

Patients: Eighteen critically ill adult patients with acute respiratory failure or heart failure, and 12 patients with sleep apnea (mean ± SD apnea/hypopnea index, 43 ± 24 events per hour).

Measurements: Continuous measurements were performed over several hours by the novel heated (temperature, 42°C) earlobe sensor (TOSCA; Linde Medical Sensors; Basel, Switzerland), incorporating electrochemical and optical elements for carbon dioxide measurement (PtcCO2) and pulse oximetry (SpO2), respectively. The data were compared to the results of repeated arterial blood gas analyses in critically ill patients and to simultaneous nocturnal pulse oximetry performed with different devices with earlobe or finger sensors in sleep apnea patients.

Results: In critically ill patients, the mean difference and limits of agreement (bias ± 2 SD) of transcutaneous PtcCO2 vs arterial PaCO2 were 3 ± 7 mm Hg; the corresponding values for changes in PtcCO2 vs PaCO2 were 1 ± 6 mm Hg. The bias ± 2 SDs for pulse oximetric SpO2 vs arterial oxygen saturation (SaO2) were 1 ± 4%. In sleep apnea patients, the combined earlobe sensor identified more transient oxygen desaturations, and the rate of change in oxygen saturation during events was greater compared to those with other tested pulse oximeters, indicating a faster response.

Conclusions: Due to its ability to accurately assess both ventilation and oxygenation by a single transcutaneous sensor, the described noninvasive monitoring technique is a valuable tool for respiratory monitoring with potential applications in critical care and sleep medicine.

(CHEST 2005; 128:1291–1296)

Key words: capnometry; carbon dioxide; critical care; oxygenation; physiologic monitoring; pulse oximetry; sleep apnea; sleep medicine; ventilation

Abbreviations: PtcCO2 = transcutaneous carbon dioxide tension; SaO2 = arterial oxygen saturation; SpO2 = pulse oximetric saturation

Noninvasive respiratory monitoring has broad applications in the emergency department, in perioperative and intensive care, and for the evaluation of sleep-related breathing disturbances. Whereas arterial oxygen saturation (SaO2) is commonly estimated by pulse oximetry,1 PaCO2 may be estimated from end-tidal carbon dioxide tension2 or transcutaneous carbon dioxide tension (PtcCO2).3–6 Since alterations in ventilation/perfusion matching7 and the use of noninvasive mask ventilation may reduce the correlation of end-tidal carbon dioxide tension with PaCO2, transcutaneous monitoring of PtcCO2 is increasingly used if the rapid tracking of transient fluctuations of PaCO2 is not essential.

Previous transcutaneous blood gas sensors, which were mainly used in pediatric care, have incorporated PtcCO2 in combination with transcutaneous
partial pressure of oxygen measurement. However, in adults, transcutaneous partial pressure of oxygen depends heavily on local skin perfusion and does not reliably reflect systemic PaO₂. Recently, a novel combined sensor for the measurement of both PtcCO₂ and pulse oximetric saturation (SpO₂) [TOSCA; Linde Medical Sensors; Basel, Switzerland] has been developed. It contains an electrochemical electrode (for PtcCO₂ measurement), a light emitter/sensor (for SpO₂ measurement), and a heating element (to increase local perfusion). The small size of the sensor allows convenient placement on the earlobe. Since the principles of the noninvasive monitoring of ventilation and oxygenation with a single cutaneous sensor are sound, and since the initial results obtained in healthy subjects and patients during anesthesia were promising, we performed a clinical evaluation of the novel sensor in the following two settings: (1) in critically ill adult patients, the accuracy of PtcCO₂ and SpO₂ measurements by the novel sensor was compared to PaCO₂ and SaO₂ measurements from blood samples repeatedly drawn from indwelling arterial lines; and (2) in patients with obstructive sleep apnea syndrome, the response characteristics of SpO₂ by the novel sensor were compared to those of several other pulse oximeters during rapid fluctuations in arterial oxygenation. In addition, the effect of sensor temperature on pulse oximeter performance was evaluated by comparing SpO₂ measured simultaneously by a heated and a nonheated earlobe sensor.

Materials and Methods

Patients

Eighteen critically ill patients with indwelling arterial lines were studied in the ICU. Their mean (± SD) age was 62.6 ± 14 years. Sixteen patients had acute respiratory failure; 2 patients had experienced an acute myocardial infarction. Fifteen patients were receiving mechanical ventilation, and 9 patients required inotropic and vasoactive drug treatment.

Twelve patients with obstructive sleep apnea syndrome were studied during nocturnal polysomnography or with limited sleep studies lasting over at least 6 h. SpO₂ measurements made with the TOSCA sensor were compared with corresponding values obtained simultaneously by the following pulse oximeters: (1) Ohmeda Biox 3740 (Datex-Ohmeda; Madison, WI) with an earlobe sensor placed on the contralateral lobe; (2) Datex-Ohmeda 3740 with finger sensor; (3) Nellcor N-395 (Nellcor; Pleasanton, CA) with finger sensor; and (4) Masimo Radical (Masimo; Irvine, CA) with finger sensor. The Datex Ohmeda 3740, the Masimo Radical, and the TOSCA oximeters were operated in their fastest response mode (ie, 3, 2, and 2 s averaging time, respectively). The response mode of the Nellcor N-395 is not modifiable, and the averaging time is not stated in the user manual. The allocation of sensors of different devices to fingers 2 to 4 of the same hand was done at random, and the sensors were covered by opaque dressing to prevent cross-talk.

Data Analysis

The data were summarized as the mean ± SD, and as medians and quartiles (for non-normally distributed values). For critically ill patients, agreement between PtcCO₂ and SpO₂ by ear sensor with corresponding values of PaCO₂ and SaO₂ by arterial blood analysis, respectively, were evaluated by computing the mean difference and limits of agreement (ie, bias ± 2 SDs). In sleep apnea patients, 30 min of recordings with most pronounced repetitive oxygen desaturations were analyzed for each patient. The data were down-sampled to 1 Hz. The delay (phase lag) in SpO₂ time series from different devices vs that from TOSCA was determined as the lag that provided the maximal coefficient of cross-correlation. A customized software identified desaturation events of > 3% from baseline, minimal SpO₂ (nadir), and the slope (rate of fall) of SpO₂ during events, as previously described. Briefly, the rolling baseline SpO₂ was defined as the mean of the highest 15% of SpO₂ values within the previous 5 min. A desaturation event was defined as a drop in SpO₂ below baseline level by > 3% to a nadir, which was followed by a rapid increase in SpO₂ of ≥ 3% within 10 s. Differences between values measured by different methods were compared by Student t test or Wilcoxon matched pairs tests, as appropriate. Significance was assumed at p < 0.05.
Results

Results in Critically Ill Patients

In the 18 patients, a total of 80 paired measurements by the earlobe sensor and by arterial blood gas analysis were obtained (mean, 4.4 ± 0.7 paired observations per patient) over a mean observation period of 160 ± 48 min. Nine patients received treatment with vasoactive drugs (i.e., IV norepinephrine, 3 to 48 μg/min; or dobutamine, 100 to 300 μg/min). The observed range in PaCO₂ was 22 to 59 mm Hg. There was close agreement between PtcCO₂ and PaCO₂ values with a minor bias of 3 mm Hg (p < 0.05) and limits of agreement of ±7 mm Hg (Fig 1). Agreement between PtcCO₂ and PaCO₂ did not differ among patients with and without vasoactive drug treatment bias and limits of agreement, 3 ± 6 mm Hg vs 3 ± 8 mm Hg, difference was not significant). The observed range of changes in PaCO₂ during repeated measurements was -17 to +10 mm Hg, and agreement among the changes in PtcCO₂ and PaCO₂ was also close (bias and limits of agreement, 1 ± 6 mm Hg; difference was not significant).

The range of observed SaO₂ was 88 to 100%. The bias and limits of agreement of SpO₂ measured by the TOSCA sensor vs SaO₂ measured by cooximetry were -1 ± 4% (p < 0.05) for all patients, and the corresponding values were similar for patients receiving and not receiving vasoactive drugs (-1 ± 4% vs -2 ± 4%, respectively; difference was not significant).

Results in Sleep Apnea Patients

The sensor was well tolerated in all patients over the duration of the overnight sleep studies. The pulse oximeter response characteristics of the various devices and sensors applied in 12 patients with obstructive sleep apnea syndrome are summarized in Table 1. The mean baseline SpO₂ measured by the TOSCA sensor was 97 ± 2%. Pulse oximetry performed by the earlobe sensor of the TOSCA device, and the finger sensor of the Masimo Radical device revealed a significantly higher number of desaturation events (i.e., SpO₂ dips of >3%), steeper desaturation slopes, and lower SpO₂ nadirs during events compared to the other earlobe and finger sensors. SpO₂ values measured with all different pulse oximeters and sensors were significantly correlated with the signal from the TOSCA sensor if the relative phase shift was compensated by cross-correlation analysis (Table 1). Visual and cross-correlation analysis revealed that the signal of the TOSCA sensor was leading, followed by the ear sensor of the Datex-Ohmeda 3740 with a modest delay of 5 s, and the finger sensor of the Datex-Ohmeda 3740, the Masimo Radical, and the Nellcor 395, with longer delays of 18 to 19 s (Fig 2, Table 1).

In seven patients, the comparison of SpO₂ measured by a heated (temperature, 42°C) TOSCA sensor with corresponding values by an unheated TOSCA sensor revealed no significant differences, neither in the number of desaturation events nor in the slope and nadir of SpO₂ during desaturation events.
The median of maximal cross-correlation coefficients between the SpO2 values determined by the two sensors was 0.93 (quartile range, 0.57 to 0.98; \( p < 0.05 \) for all individuals), and the unheated sensor lagged between 1 and 1 s.

In three patients in whom the ratio between the pulsatile and nonpulsatile components of infrared extinction was computed as a measure of peripheral perfusion, the individual mean values over the monitoring period were consistently higher for the heated sensor (0.9%, 3.0%, and 3.1%, respectively, in patients 1, 2, and 3) than for the unheated sensor (0.5%, 1.6%, and 1.2%, respectively in patients 1, 2, and 3). Since the pulsatile component of the signal is essential for SpO2 measurement, this corresponds to an improvement of the pulse oximeter signal/noise ratio by a factor of 1.8, 1.9 and 2.6 in these three patients, respectively.

**Discussion**

We evaluated the performance of a novel combined earlobe sensor for noninvasive transcutaneous monitoring of SpO2 and PtcCO2 in two different settings. The studies in critically ill patients revealed a clinically acceptable agreement of PtcCO2 and its changes, and of SpO2 by the transcutaneous sensor with simultaneous measurements made by the “gold standard” (ie, the analysis of arterial blood samples). The observations in patients with sleep apnea provided the opportunity to demonstrate favorable response characteristics of SpO2 by the novel, heated earlobe sensor in comparison with several other pulse oximeters with unheated ear and finger probes during rapid fluctuations in SaO2. Our data suggest that ventilation and oxygenation can be accurately and noninvasively monitored with a single combined earlobe sensor.

Several previous studies in adults with chronic respiratory failure or during acute critical illness or anesthesia,4,5,18 and in mechanically ventilated children6,10,20 revealed a clinically acceptable agreement between PtcCO2 values measured with a sensor at the trunk or extremity and PaCO2 values obtained from the analysis of arterial blood samples. The range of observed bias for PtcCO2 in the cited studies was \(-3\) to +3 mm Hg, and the range of limits of agreement was \(\pm 4\) to \(\pm 7\) mm Hg. The sensor used in the current investigation to monitor critically ill patients.
revealed a similar accuracy of PtcCO₂ (i.e., a bias of +3 mm Hg that was statistically significant but clinically of minor relevance, and limits of agreement of ±7 mm Hg). Of note, these results were achieved with a sensor heated to a temperature of only 42°C (rather than to 43 to 45°C as in the cited studies) in order to enhance patient comfort and to reduce the risk of skin trauma. In contrast to some earlier observations,²¹ the accuracy of PtcCO₂ did not differ among patients with or without vasoactive drug therapy (Fig 1), suggesting that the accurate estimation of PtcCO₂ is feasible in hemodynamically compromised patients. In terms of clinical decision making, the ability of a technique to detect changes in measured variables is important. Therefore, we evaluated the accuracy of the novel sensor in detecting changes in PaCO₂ occurring spontaneously or in response to therapeutic interventions in the critically ill patients. The nonsignificant bias and the limits of agreement of changes in PtcCO₂ vs changes in PaCO₂ (i.e., ±6 mm Hg) indicated that clinically relevant changes in PaCO₂ of >6 mm Hg can be identified by the transcutaneous sensor with a high level of confidence, and this performance of the noninvasive TOSCA sensor was similar to that of an intra-arterial probe for continuous blood gas analysis.²²

Compared to SaO₂ obtained by co-oximetry of arterial blood in critically ill patients, the SpO₂ determined by the TOSCA sensor revealed a bias of 1% (p < 0.05), and limits of agreement of ±4%. This is consistent with earlier results obtained with a prototype of the current sensor in healthy subjects and anesthetized patients,¹¹,¹²,¹³ and with studies evaluating other pulse oximeters.¹

Since the SaO₂ in critically ill patients was fairly stable and was maintained at >88%, we further evaluated the pulse oximetry performance of the novel sensor in patients with obstructive sleep apnea. This condition is typically associated with rapid fluctuations in SpO₂. We found that SpO₂ measured by the novel ear sensor significantly correlated with corresponding values measured by the other tested pulse oximeters if the phase shift among devices and sensors was accounted for (Table 1). This analysis also demonstrated that the TOSCA sensor detected SpO₂ desaturation events significantly earlier than the finger and earlobe sensors of the other devices. This was partly related to the greater circulation time for the finger compared to the earlobe, as evidenced by the greater delay of the Datex-Ohmeda 3740 signal when used with a finger sensor compared to an earlobe sensor (i.e., a delay of 18 vs 5 s relative to the TOSCA signal) [Table 1]. Nevertheless, similar lag times of 18 to 19 s of various pulse oximeter signals with finger probes together with the 5-s lag of the Datex-Ohmeda 3740 signal with an earlobe probe indicate faster processing for the TOSCA signal. Rapid response characteristics of a pulse oximeter are desirable not only for the timely detection of deterioration in the status of a critically ill patient, but they also provide a greater sensitivity for the capture of transient drops in SpO₂ such as desaturation events in sleep apnea patients. Thus, the TOSCA and Masimo Radical devices identified a significantly greater number of desaturation events that had steeper slopes and reached lower nadirs than corresponding events recorded by the Datex-Ohmeda 3740 and Nellcor N-395 devices (Table 1). These observations emphasize the impact of pulse oximetry signal processing on the outcome of diagnostic pulse oximetry for sleep apnea case finding and severity grading.²⁴

We found an equivalent performance for heated vs unheated earlobe sensors in terms of SpO₂ response characteristics, suggesting that a higher probe temperature was not essential for pulse oximetry in the studied setting. Yet, heating the probe is crucial for transcutaneous CO₂ monitoring³ and might be advantageous for pulse oximetry in patients with impaired peripheral perfusion since it enhances pulsatile blood flow,¹¹ as illustrated in three patients by an increase in the fraction of pulsatile infrared extinction by a factor of 1.8 to 2.6 in the heated vs the nonheated earlobe sensor.

In conclusion, we found that the novel combined SpO₂ and PtcCO₂ sensor accurately monitored SaO₂, PaCO₂, and their changes. Compared to other pulse oximeters, the novel sensor had favorable dynamic response characteristics. The current data corroborate previous results obtained with a prototype of the sensor in healthy subjects and patients during anesthesia,¹¹,¹²,¹³ and extends its validation to the application in critically ill patients, and for tracking rapid fluctuations in SpO₂ in patients with sleep-disordered breathing. Due to its ability to noninvasively assess both ventilation and oxygenation in addition to pulse rate by a single transcutaneous sensor, the described noninvasive monitoring technique is a convenient and valuable tool for respiratory monitoring with potential applications in critical care, anesthesia, and sleep medicine.

ACKNOWLEDGMENT: We are grateful for the technical assistance provided by C. Morger, and M. Vignjevic, sleep laboratory, Pulmonary Division, University Hospital of Zurich, Linde Medical Sensors, Basel, Switzerland, provided the TOSCA device used in this study and an unconditional grant to the Pulmonary Division, University Hospital of Zurich.

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