Combined Pulse Oximetry/Cutaneous Carbon Dioxide Tension Monitoring during Colonoscopies: Pilot Study with a Smart Ear Clip

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Abstract

Background: We compared the accuracy and practicability of a new combined ear sensor device measuring pulse oximetry and transcutaneous carbon dioxide tension. Methods: Validation studies were done by comparing the results of the combined sensor with arterial blood gas measurements. In an observational part, monitoring data were obtained from 25 patients undergoing colonoscopy, sedated with midazolam and alfentanil and from 8 patients without sedation. Results: There was an excellent correlation between the oxygen saturation and carbon dioxide tension measurements comparing the combined sensor with arterial blood gas analysis (R 0.96 and 0.93, respectively). A mean rise in transcutaneous carbon dioxide tension of 7.6 mm Hg was detectable during sedation with midazolam/alfentanil and of 2.3 mm Hg without sedation. Conclusion: Combined POX/PcCO₂ monitoring at the ear lobe is a novel approach to improve patient safety during sedation and may be helpful in preventing an unintentional slide into a state of deep sedation with impairment of ventilation.

Introduction

Endoscopic procedures are commonly performed using sedation. As drug-induced respiratory depression is a major cause of sedation-associated morbidity, pulse oximetry (POX) has been established as standard practice to detect hypoxemia [1–3]. However, oxygen saturation measured with POX (SpO₂) provides only a surrogate measure of arterial oxygen saturation (SaO₂) which itself does not completely reflect ventilation. Due to the S-shape of the oxygen dissociation curve, large changes in the partial oxygen tension (PaO₂) may remain unnoticed over a period of time if monitoring is carried out with POX alone [4].

In the last years, new anesthetic drugs and advanced interventional techniques are increasingly used which may lead to deeper levels of sedation [5, 6]. Although several large clinical trials have recently demonstrated the
safety of new drugs (e.g. propofol) under careful patient selection and conventional surveillance, there is still an ongoing debate on the risk that patients may unintentionally slide into a level of deep sedation or even anesthesia where vital functions may be seriously impaired [1, 7–13]. Many doubts regarding the use of these drugs by non-anesthesiologists (e.g. gastroenterologists) could therefore be eliminated, if POX could be supplemented with monitoring techniques providing more specific information on ventilation.

As hypoventilation is directly reflected by an increase in arterial carbon dioxide tension (PaCO₂), capnography suggests itself as an additional monitoring parameter, which furthermore demonstrates respiration activity breath by breath [1, 4, 14]. Actually in intubated patients or under stable conditions without oral leakage the measurement of end-tidal carbon dioxide tension (PetCO₂) in the exhaled air shows an adequate correlation with PaCO₂ [4]. Unfortunately, in the state of moderate or deep sedation during diagnostic or therapeutic procedures (e.g. ERCP or colonoscopies), regular breathing is often disturbed by moving, squeezing, coughing or changes between nose and mouth ventilation causing leakage and therefore artifacts or misinterpretation of data acquired with PetCO₂. These problems often restrict the use of side-stream capnography in clinical practice, although the American Society of Anesthesiologists as well as the American Society of Gastrointestinal Endoscopy (ASGE) have suggested in their guidelines that extended monitoring with capnography ‘should be considered’, in deep sedation [1, 5].

Transcutaneous carbon dioxide tension measurement (PcCO₂) has previously been introduced in gastrointestinal endoscopy, but the limiting factors for the routine use of this monitoring technique included difficult calibration and long-lasting equilibration procedures [15]. Recently, new technological developments such as the combined pulse oximetry and carbon dioxide tension earlobe sensor used in this study have reduced the size of monitoring tools and overcome prior practical obstacles [16].

The aims of our study were (1) to examine the accuracy of the earlobe POX/PcCO₂ sensor compared with standard POX and blood gas analysis and (2) to evaluate the practicability of its use while monitoring sedations during colonoscopies.

### Patients and Methods

#### Patients
The accuracy of the combined POX/PcCO₂ earlobe sensor used in this study was evaluated by comparing the values with simultaneously obtained results from arterial blood gas analysis. Measurements were done in 33 patients from the Division of Respiratory Medicine who were scheduled to undergo one or repeated routine arterial punctures for evaluation of diverse respiratory diseases.

In a follow-up prospective observational study the value of continuous monitoring with the combined SpO₂/PcCO₂ earlobe sensor was assessed in 33 patients (48% female; mean age ± SD 59 ± 12.9 years) undergoing colonoscopy under sedation and analgesia with midazolam combined with alfentanil (4 µg/kg BW) (n = 25 consecutive patients) or without any sedation or analgesia (n = 8). From all patients a short personal history was obtained and general physical condition was assessed using the American Society of Anesthesiologists (ASA) classification. Exclusion criteria were: (1) known history of intolerance to midazolam or alfentanil; (2) age less than 18 or more than 85 years; (3) ASA score IV or V, and (4) intravenous drug abuse. As a standard procedure sedated patients received 3 liters/min supplemental oxygen. The first dose of midazolam was administered strictly 1 min after alfentanil was given. Further boluses were given according to clinical response at intervals of at least 1 min.

Eight patients who preferred undergoing colonoscopy without sedation or analgesia served as a control group for changes of physiological parameters.

The study protocol was approved by the local ethics committee and written informed consent was obtained from the patients before study enrollment.

#### Methods
We used a newly developed combined POX/PcCO₂ sensor (VCap® Sign™, Sentec AG, Therwil, Switzerland) weighing 3 g that was placed at the right earlobe with a dedicated ear clip (fig. 1a). This fully digital sensor combines the elements of an electrochemical Severinghaus-type carbon dioxide tension sensor with those of conventional optical POX sensors, thus providing noninvasive and continuous estimation of PaCO₂ and SaO₂ (fig. 1b) [17–19]. It is warmed to a constant surface temperature of 42 °C to improve local arterIALIZation and to accelerate carbon dioxide diffusion. SpO₂ values are available immediately, while PcCO₂ values need a certain equilibration time. The system is designed to be ‘ready-for-use’ by automated recalibration every time the sensor is placed on the docking station between measurements [20].

For the validation part of the study, 50 earlobe PcCO₂ and SpO₂ readings were compared with 50 PaCO₂ and SaO₂ values obtained simultaneously by arterial puncture (average of blood-gas analyzers ABL 500 and ABL 725, Radiometer, Copenhagen, Denmark).

In the observational part, readings from the POX/PcCO₂ sensor (placed at the right earlobe) and a standard pulse oximeter probe (Nellcor N-595, Durasensor DS-100A, Nellcor Inc., Pleasanton, Calif., USA) placed on the left index finger were simultaneously and continuously recorded and stored on a personal computer. Furthermore end-tidal PCO₂ (PetCO₂) in the exhaled breath air was measured and recorded using side-stream technique with a handheld capnograph (Nellcor NPB 70) and a combined mouth and nose sampling probe (Smart CapnoLine™ O₂). All collected data were visualized with statistic graphics software (Igor Pro 4.01, WaveMetrics Inc.,

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Lake Oswego, Oreg., USA). Values at defined time points were thereafter identified manually.

**Statistical Analysis**

Agreement of SpO2 and PcCO2 values from the ear sensor with SaO2 and PaCO2 values obtained from arterial blood gas analysis were analyzed using correlation (r) and limits of agreement as described by Bland and Altman [21]. In the observational part all parameters were analyzed with descriptive statistics (mean ± SD).

**Results**

Correlation between 50 simultaneous arterial blood gas samplings and transcutaneous measured carbon dioxide tension and oxygen saturation were excellent over a wide range of PaCO2 and SaO2. The Pearson correlation coefficients were R = 0.96 and R = 0.93, respectively. With Bland-Altman analysis, comparing the PcCO2 (combined ear sensor) and the arterial PaCO2 values, the mean difference was 0.4 mm Hg with limits of agreement of +6.3 to −5.5 mm Hg (± 2 SD) (fig. 2). For SpO2 (com-
Fig. 3. Typical course of SpO2 (upper part) and PcCO2 (lower part) following administration of midazolam. The black solid lines are the SpO2 data points from the POX/PcCO2 ear sensor and the grey solid line from the finger pulse oximeter (note the time lag). Horizontal shaded areas indicate the baseline of PcCO2 levels and the vertical shaded areas indicate the times when intermittent sedative drug doses (d.o.s.) were administered. The increase of PcCO2 reflects hypoventilation even under satisfactory SpO2 values above 97%.

Table 1. Demographic data of colonoscopy patients

<table>
<thead>
<tr>
<th></th>
<th>M + A (n = 25)</th>
<th>No sedation (n = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (SD)</td>
<td>59 (13)</td>
<td>63 (12)</td>
</tr>
<tr>
<td>M:F (n)</td>
<td>10:15</td>
<td>3:5</td>
</tr>
<tr>
<td>Smokers</td>
<td>4 (16%)</td>
<td>1 (13%)</td>
</tr>
</tbody>
</table>

M + A = Midazolam + alfentanil.

Table 2. Ventilation measurements during procedures

<table>
<thead>
<tr>
<th></th>
<th>M + A (n = 25)</th>
<th>No sedation (n = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a SpO2 at baseline and changes during endoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SpO2 at baseline, %</td>
<td>98 (1)</td>
<td>98 (1)</td>
</tr>
<tr>
<td>Mean decrease of SpO2, %</td>
<td>4 (3)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>b Profile of PcCO2 during the procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PcCO2 at baseline</td>
<td>34.4 (4.1)</td>
<td>36.7 (3.4)</td>
</tr>
<tr>
<td>Maximal PcCO2</td>
<td>42.5 (5.6)</td>
<td>39.0 (5.9)</td>
</tr>
<tr>
<td>Mean rise in PcCO2</td>
<td>7.6 (3.4)</td>
<td>2.3 (2.4)</td>
</tr>
<tr>
<td>PcCO2 at the end</td>
<td>39.4 (4.8)</td>
<td>37.1 (4.9)</td>
</tr>
</tbody>
</table>

1 Mean (SD).
2 Mean (SD) mm Hg.
M + A = Midazolam + alfentanil.

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The mean equilibration time until a stable PcCO2 value could be obtained (depicted as a stable plateau of the PcCO2 curve) was 4.9 (SD 1.7) min. This time was also needed if during measurement a short disconnection of the sensor from the ear skin occurred.

Demographic characteristics of the study groups are shown in table 1. In all patients who were administered sedation, the PcCO2 values increased by a mean of 7.6 (SD 3.4) mm Hg reflecting hypoventilation even when oxygen saturation showed stable values above 97% (fig. 3). For non-sedated patients the mean rise in PcCO2 was only 2.3 (SD 2.4) mm Hg. The mean SpO2 values at baseline and the mean decrease during sedation are shown in table 2a, a profile of mean PcCO2 values during the procedure is shown in table 2b.

While the values of PcCO2 and PetCO2 often correlated well during rather stable and controlled ventilation stages at the beginning or at the end of a procedure or in non-sedated patients, sedation and endoscopy often lead to disturbance of the side-stream capnography system resulting in false alarms and misleading results (fig. 4).
**Discussion**

The present study shows (1) that values recorded with the combined POX/PcCO₂ sensor correlate excellently with blood gas analysis; (2) that in sedated patients undergoing colonoscopy hypoventilation reflected by retention of PCO₂ can easily be detected by the use of a combined POX/PcCO₂ ear sensor, and (3) that monitoring with the combined POX/PcCO₂ sensor is more specific in the detection of hypoventilation than standard POX alone.

Correlation between SpO₂ of the combined ear sensor and arterial SaO₂ values was excellent. We attribute this to the warming of the measurement side resulting in an increased local perfusion and, hence, well-defined pulsatile signals [20]. In the present study in the peripherally well-perfused patients, the faster response time with regards to the SpO₂ values at the ear versus left index finger by an average of 30 s is mainly site related [22]. In patients with peripheral vasoconstriction or low perfusion the time lag between ear and finger sensor readings would even be larger. We therefore conclude that more centrally placed ear sensors offer a clinically relevant advantage over finger sensors when monitoring patients in situations where rapid detection of hypoxemia is critical.

There was an excellent correlation between the PcCO₂ of the combined ear sensor and arterial PaCO₂ over a wide range of PaCO₂ (21–85 mm Hg). In a previous study including twelve healthy volunteers it was reported that the PCO₂ sensor segment is as fast as the SpO₂ sensor segment. Significant changes in PCO₂ as well as SpO₂ readings upon breath holding (e.g. simulated apnea) were reported to be detected after 35 s [16]. As compared to traditional use of transcutaneous measurements we attribute this significantly faster PcCO₂ response to the measurement site (earlobe versus chest, upper arms and thighs) as well as to the reduced diffusion distance in a ear-clip sensor application setting as compared to an adhesive-ring setting involving a relatively large volume of contact gel through which carbon dioxide must diffuse.

A further detail that may be relevant for the acceptance of the method in daily practice is the reduced onset time as compared to previous studies with traditional PcCO₂ sensors [23]. The onset time is defined as the time from sensor application until equilibration of the skin PcCO₂ and the PaCO₂ in the sensor is achieved. In this study the onset time was about 5 min.

The clinical importance of detecting profound hypoventilation occurring in patients undergoing gastrointestinal endoscopy through carbon dioxide retention has been discussed in earlier studies [4, 15, 23, 24]. With the practical recommendation and the increased use of supplemental oxygen to prevent hypoxemia [25], the measurement of carbon dioxide tension seems to be more relevant because hypoventilation is not reflected by pulse oxime-
try. These findings have been confirmed in our study where obvious changes in \( \text{PcCO}_2 \) levels were observed in all sedated patients, even with stable values of oxygen saturation around 100%. Our results which show a mean \( \text{PcCO}_2 \) peak increase of 7.6 (SD 3.4) mm Hg with alfentanil/midazolam are well comparable with those (6.8 mm Hg) reported by Freeman et al. [15] in 30 patients undergoing colonoscopy who were sedated with fentanyl and/or midazolam. In longer-lasting ERCP procedures with a tendency to deeper sedation even higher mean peak increases have been reported [15, 23]. Miner et al. [4] have reported an increase of 9.4 mm Hg in patients administered sedation during painful procedures in emergency departments.

It was the focus of this study to evaluate the combined POX/\( \text{PcCO}_2 \) sensor and not to compare it with side-stream capnography. Therefore, a comparable judgment cannot be made. Both techniques may have their advantages: while the side-stream capnograph provides on its monitor a visual graph of every registered breath, in our experience the cutaneous \( \text{PcCO}_2 \) measurement seems to be more stable and less susceptible to interferences.

Apnea or prolonged desaturations (<90% for more than 20 s) were not observed during this pilot study. We can therefore not state if the monitoring of \( \text{PcCO}_2 \) adds a major additional benefit for patient safety compared with POX alone. Nelson et al. [23] found conflicting results with respect to the benefit of \( \text{PcCO}_2 \) monitoring to guide sedation and to avoid respiratory depression during ERCP. While he could avoid maximal rises of \( \text{PcCO}_2 \) of more than 40 mm Hg, the occurrence of desaturations below 80% did not differ significantly. In accordance with the results of Miner et al. [4] with end-tidal carbon dioxide monitoring, we postulate that target values of \( \text{PcCO}_2 \) like ‘below 50 mm Hg’ or an absolute change of ‘less than 10 mm Hg from baseline’ may support the safe administration of sedative drugs during colonoscopies. Especially the decision about administration of an additional bolus of the sedative agent during the procedure may be supported by the course of \( \text{PcCO}_2 \) values. Additional larger studies would be needed to confirm this assumed benefit on patient safety.

We conclude that combined POX/\( \text{PcCO}_2 \) monitoring at the earlobe is a novel approach to detect hypoventilation and therefore might improve patient safety during sedation. It may be used to titrate the administration of sedative drugs to prevent an unintentional slide into deep sedation or anesthesia with the risk of developing apnea. Larger studies, especially with short-acting sedative drugs like propofol, are needed to confirm the clinical benefit of this novel technique.

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References