Evaluation of a New Combined Transcutaneous Measurement of PCO₂/Pulse Oximetry Oxygen Saturation Ear Sensor in Newborn Patients

Vera Bernet-Buettiker*; Maria J. Ugarte*; Bernhard Frey*; Maja Isabelle Hug*; Oskar Baenziger*; and Markus Weiss‡

ABSTRACT. Objective. Arterial oxygen saturation (SaO₂) and arterial carbon dioxide partial pressure (PaCO₂) are 2 of the most important respiratory parameters in the treatment of critically ill neonates. Noninvasive monitoring of these parameters is desirable for continuous estimating of the respiratory status and reducing blood loss because of repeated blood gas analyses. Transcutaneous measurement of PCO₂ (PtcCO₂) represents a simple and noninvasive technique for continuous monitoring of ventilation. However, sensor preparation, positioning, taping, and repeated changes of the sensor location make the handling difficult and complicate its use in the neonatal care unit. Recently, a new sensor for combined assessment of pulse oximetry oxygen saturation (SpO₂) and PtcCO₂ has been introduced (TOSCA Monitor; Linde Medical Sensors, Basel, Switzerland). The monitor combines pulse oximetry and PtcCO₂ measurement in a single ear sensor, which works at 42°C to enhance blood flow in capillaries below the sensor.

Methods. In a prospective, open, nonrandomized study of 60 ill neonates, the new ear sensor for combined assessment of SpO₂ and PtcCO₂ at 42°C was tested. The sensor was adapted to the ear of a neonate with a Vaseline layer (Convatec; Princeton, NJ). Data obtained from the ear sensor were compared with SpO₂ Finger/Heel and SaO₂ and PaCO₂ obtained from arterial blood gas in 30 patients and with a capillary blood gas in an additional 30 patients using Bland Altman bias analysis. Data are presented as median (range).

Results. The postconceptional age of the patients was 38.3 weeks (range: 28 5/7–40 5/7) in the arterial blood sample group and 37.9 weeks (range: 29 6/7–41 0/7) in the capillary group. Age of the newborns studied was 3.5 days (range: 1–28) in the arterial group and 2.76 kg (range: 1.0–3.71) in the other group. Three patients had weights of <1500 g. Twenty-one of 60 patients were conventionally ventilated, 4 patients received high-frequency oscillation, and 35 were not ventilated. Mean difference (bias) and precision (2 SD of the mean difference) between PtcCO₂ TOSCA and PaCO₂ were −0.09 kPa (−0.67 mm Hg) and 1.11 kPa (8.07 mm Hg), respectively. SpO₂ assessment by the TOSCA revealed slightly higher values compared with SaO₂ (bias: −0.48%), whereas SpO₂ Finger/Heel values were slightly lower than SaO₂ (bias: 0.52%).

Conclusion. The TOSCA monitor with the ear sensor adapted to ears of neonates allows reliable estimation of SaO₂ and PaCO₂. A potential benefit is the reduction in motion artifacts because of less head movement in newborns and that only a single cable leads form the patient to the monitor. In addition, the sensor is not removed for chest radiograph or for nursing the infant on his or her parent’s lap. Long-term studies in a large population with continuous measurements are required to confirm these preliminary findings and to elucidate the benefits in detection of respiratory deterioration and the potential side effects of this sensor. Pediatrics 2005;115:e64–e68. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2004-0946; noninvasive monitoring, oxygenation, pulse oximetry, carbon dioxide, neonate.

ABBREVIATIONS. SaO₂, arterial oxygen saturation; PaCO₂, partial arterial pressure of carbon dioxide; PtcCO₂, transcutaneous measurement of Pco₂.
unit. Recently, a new sensor for combined assessment of SpO2 and Ptcco2 has been introduced (TOSCA Monitor; Linde Medical Sensors, Basel, Switzerland). The monitor combines pulse oximetry and Ptcco2 measurement in a single ear sensor, which works at 42°C to enhance blood flow in capillaries below the sensor.

The monitor has been tested in adults and children who underwent general anesthesia. So far, no data are available about suitability and reliability of the monitor in newborn infants. Thus, the aim of the present study was to evaluate the performance and reliability of the SpO2 and Ptcco2 reading of this monitor in newborns.

METHODS

This study was approved by the Hospital Ethics Committee, and in all patients, informed parental consent was obtained. Sixty neonates who were hospitalized in either our intensive care or our neonatal unit were enrolled in this study.

The sensor was attached to the ear lobe using an adhesive holder that has integrated a reflective element positioned onto the inner surface of the ear lobe, to allow transmissive-reflective pulse oximetry with red-infrared absorption analysis of the arterial pulse signal. The sensor comprises the basic element of a Severinghaus-type Ptcco2 sensor and the basic elements of a pulse oximeter sensor. The sensor (and also the pH electrode) was miniaturized to fix it onto the ear lobe. A new assembling of the sensor, which constitutes an electrolyte solution, a spacer, and a Teflon membrane, has to be done every 14 days. Calibrations are automatically performed in 1 calibration gas by the system. In vitro response time and drift are typically below 50 s and below 0.5% per hour during the 14 days, respectively.

Ptcco2 measurement is based on that carbon dioxide diffuses through body tissues and can be detected by a sensor with a gas-permeable membrane at the skin surface. The system is equipped with an integrated calibration unit for fully automatic calibration before measurements and with a built-in self-check function. The sensor has to be remembraned. Calibrations are automatically performed in 1 calibration gas by the system. In vitro response time and drift are typically below 50 s and below 0.5% per hour during the 14 days, respectively.

Statistical Analysis

Data are presented as median and range. Ptcco2 TOSCA, SpO2 TOSCA, PtcO2 right hand or feet (Pulse oximeter Module Solar 8000; Marquette Hellige GmbH, Freiburg, Germany; standard device in our unit), perfusion quality (measured by the TOSCA device), mean arterial blood pressure, heart rate, and body temperature. Patient characteristics were noted: diagnosis, postconceptional age, postnatal age, and weight.

RESULTS

The median (range) postconceptional age of the patients was 38.3 weeks (28.5–40.5) in the arterial group and 37.9 weeks (29.6–41.0) in the capillary group. The median (range) postnatal age of the newborns studied was 3.5 days (1–28) in the arterial blood sample group (n = 30) and 6 days (2–28) in the capillary blood sample group (n = 30). The median weight (range) was 3.02 kg (1.5–4.5) in the arterial
group and 2.76 kg (1–3.71) in the other group (Table 1). Three patients had weights of <1500 g. Diagnoses of the patients with arterial blood sampling were congenital heart disease (n = 13), esophageal atresia (n = 5), respiratory distress syndrome caused by wet lung syndrome or pneumonia (n = 3), hyaline membrane disease (n = 3), necrotizing enterocolitis (n = 2), and others (n = 4; cutis laxa, asphyxia, omphalocele, and anal atresia, 1 each). In this group, 19 patients were conventionally ventilated, 4 patients received high-frequency oscillation, and 7 were not ventilated. The diagnoses of the capillary blood sampling group were hyaline membrane disease (n = 6), respiratory distress syndrome caused by wet lung syndrome or pneumonia (n = 6), asphyxia (n = 5), congenital heart disease (n = 5), sepsis (n = 4), intraventricular hemorrhage (n = 2), and others (n = 2; meconium plug syndrome and septo-optical dysplasia, 1 each). Only 2 of these patients were conventionally ventilated. Patient characteristics and measured values are given in Table 1.

Mean difference (bias) and precision (2 SD of the mean) between PtcCO2 TOSCA and PaCO2 were −0.44 kPa (3.21 mm Hg) and 0.82 kPa (6.02 mm Hg) and between PtcCO2 TOSCA and PcapCO2 were −0.09 kPa (−0.67 mm Hg) and 1.11 kPa (8.07 mm Hg), respectively (Table 2, Fig 2).

Spo2 assessment by the TOSCA revealed slightly higher values compared with SaO2 (mean difference: −0.48%), whereas Spo2 Finger/Heel values were slightly lower than SaO2 (0.52%). Precision of Spo2 TOSCA and Spo2 Finger/Heel to indicate SaO2 was similar (5.57% and 4.94%, respectively; Table 2).

**DISCUSSION**

In the present study, we evaluated reliability of the TOSCA monitor to reflect SaO2 and PaCO2 with a single ear sensor in newborns. The main finding was a good reproducibility with clinically acceptable bias and precision between PtcCO2 and Spo2 measured at the ear lobe and invasively measured values.

Measurement of capillary PaCO2 represents a common practice to estimate PaCO2 in neonates without an arterial catheter with the understanding that PaCO2 is up to 0.5 kPa (3.7 mm Hg) higher than invasively measured PaCO2. Similarly, PtcCO2 TOSCA values were 0.44 kPa (3.2 mm Hg) higher than PaCO2 values and comparable with PcapCO2 values in our study. In fact, comparison of PtcCO2 TOSCA and PcapCO2 values revealed a negligible bias, presumably because both measurements represent PCO2 of the capillary bed. The relatively large limits of agreement for this comparison are caused by the fact that both methods represent estimation techniques for PaCO2 and precision of PcapCO2 versus PtcCO2 TOSCA values were within those reported by other investigators for capillary versus arterial PaCO2 (Table 3). Agreement of PtcCO2 TOSCA values and PaCO2 was superior to that reported in the literature for capillary PaCO2 and PaCO2 (Table 3). Estimation of SaO2 with the Spo2 TOSCA ear sensor revealed equal results to standard Spo2 monitoring (Table 3).

Our preliminary data in small infants (weight range of the whole group: 1.0–4.5 kg) demonstrate that the TOSCA ear sensor may be a reliable tool for noninvasive estimation of SaO2 and PaCO2 in newborns. The fairly wide limits of agreement when comparing with arterial values points to the fact that the primary value of this and other, similar noninvasive devices is to follow trends. The TOSCA monitor is simple to use, and the ear sensor with adhesive holder is easy to apply, even in very small infants. A potential benefit of this combined ear sensor (vs Spo2 hand/foot sensor and PtcCO2 sensor applied to the trunk, respectively) is the reduction in motion artifacts because of less head movement in newborns. In addition, the sensor is not removed for chest radiograph or for nursing the infant on his or her parent’s

**TABLE 1.** Demographic Patient Data and Measured Parameters (Median and Range)

<table>
<thead>
<tr>
<th></th>
<th>Arterial Samples (n = 30)</th>
<th>Capillary Samples (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, d</strong></td>
<td>3.5 (1–28)</td>
<td>9.1 (1–28)</td>
</tr>
<tr>
<td><strong>Postconceptional age, wk</strong></td>
<td>38.3 (28.5/7–40.5/7)</td>
<td>37.9 (26.7–41.0/7)</td>
</tr>
<tr>
<td><strong>Weight, kg</strong></td>
<td>2.02 (1.5–4.5)</td>
<td>2.76 (1–3.71)</td>
</tr>
<tr>
<td><strong>Mean arterial pressure, mm Hg</strong></td>
<td>44 (32–68)</td>
<td>44.5 (38–62)</td>
</tr>
<tr>
<td><strong>Heart rate, bpm/min</strong></td>
<td>136 (114–182)</td>
<td>140 (114–168)</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>7.37 (7.2–7.54)</td>
<td>7.39 (7.26–7.47)</td>
</tr>
<tr>
<td><strong>PaCO2, kPa/mm Hg</strong></td>
<td>5.8 (3.3–7.8) / 42.3 (24.1–56.9)</td>
<td>–</td>
</tr>
<tr>
<td><strong>PcapCO2, kPa/mm Hg</strong></td>
<td>–</td>
<td>5.77 (3.3–7.9 /42.1 (24.1–57.7)</td>
</tr>
<tr>
<td><strong>PtcCO2 TOSCA, kPa/mm Hg</strong></td>
<td>6.3 (3.4–9.0) / 46.0 (24.8–65.7)</td>
<td>6.55 (3.3–8.3 /42.1 (24.1–60.6)</td>
</tr>
<tr>
<td><strong>SaO2</strong></td>
<td>93.6 (64.7–98.7)</td>
<td>–</td>
</tr>
<tr>
<td><strong>SpO2 TOSCA</strong>%</td>
<td>94 (71–100)</td>
<td>97 (84–100)</td>
</tr>
<tr>
<td><strong>SpO2 Finger/Heel</strong></td>
<td>92 (68–100)</td>
<td>95 (82–100)</td>
</tr>
</tbody>
</table>

**TABLE 2.** Comparison of Invasively and Noninvasively Measured Values

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Bias</th>
<th>Precision</th>
<th>95% Limits of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>PcapCO2−PtcCO2 TOSCA</td>
<td>30</td>
<td>−0.09 kPa (−0.67 mm Hg)</td>
<td>1.11 kPa (8.07 mm Hg)</td>
<td>4.60–6.81 kPa (33.5–49.7 mm Hg)</td>
</tr>
<tr>
<td>PaCO2−PtcCO2 TOSCA</td>
<td>30</td>
<td>−0.44 kPa (−3.21 mm Hg)</td>
<td>0.82 kPa (6.02 mm Hg)</td>
<td>5.14–6.79 kPa (33.5–49.7 mm Hg)</td>
</tr>
<tr>
<td>SaO2−Spo2 TOSCA</td>
<td>23</td>
<td>−0.48%</td>
<td>4.94%</td>
<td>87.30–97.18%</td>
</tr>
<tr>
<td>SaO2−Spo2 Finger</td>
<td>23</td>
<td>0.52%</td>
<td>5.57%</td>
<td>86.17–97.31%</td>
</tr>
</tbody>
</table>

In 7 children, standard Spo2 equipment (Marquette) was not available.
lap. The combination of transcutaneous oxygen saturation and Ptc\textsubscript{co}\textsubscript{2} may be another advantage, because only a single cable leads from the patient to the monitor.

In this study, only single point assessments were performed but no data on long time application were obtained. Only 3 patients had weights <1500 g, and no patient with a gestational age of <28 weeks was included. Fixation might be more difficult in this group of patients. We did not compare Ptc\textsubscript{co}\textsubscript{2} TOSCA with other Ptc\textsubscript{co}\textsubscript{2} monitors. Additional studies should include long-term applications with sensor placement changes only every 12 hours, as recommended by the manufacturer, with regard to continuous reliability of Sp\textsubscript{o}2 and in particular P\textsubscript{co}\textsubscript{2} readings and to potential side effects such as inflammations or burns. These time recommendations are made for adults and children; they have not been tested on the sensitive ear lobe of neonates.

In summary, the TOSCA monitor allows reliable noninvasive estimation of Sa\textsubscript{o}2 and Pa\textsubscript{co}\textsubscript{2} with an easy-to-handle, noninvasive single sensor in the care of neonates. Additional studies with continuous, long-term measurements are required in a larger population of newborns to confirm these preliminary findings, to elucidate the benefits in detection of respiratory deterioration, and to track potential side effects of long-term sensor applications.

**ACKNOWLEDGMENTS**

The TOSCA device and disposable attachment clips have been provided by the manufacturer (Linde Medical Sensors AG, Basel, Switzerland) for the study without charge. The authors do not hold any agreement on the device and did not receive any financial support from the manufacturer for the study.

We thank P.-A. Gisiger (Linde Medical Sensors AG) for support in modifying the ear sensor for neonates and assistance during the measurements.

**REFERENCES**


![Fig 2. Bland and Altman bias plots for the comparison of Ptc\textsubscript{co}\textsubscript{2} TOSCA and Pa\textsubscript{co}\textsubscript{2}. Mean difference (bias) and precision (2 SD of the mean difference) are indicated by dotted lines.](http://pediatrics.aappublications.org/)
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