Evaluation of a New Combined Transcutaneous Measurement of \( \text{PCO}_2 \)/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 (\( \text{SaO}_2 \)) and arterial carbon dioxide partial pressure (\( \text{PaCO}_2 \)) 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 \( \text{PCO}_2 \) (Pt\( \text{CO}_2 \)) 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 (\( \text{SpO}_2 \)) and Pt\( \text{CO}_2 \) has been introduced (TOSCA Monitor; Linde Medical Sensors, Basel, Switzerland). The monitor combines pulse oximetry and Pt\( \text{CO}_2 \) measurement in a single ear sensor, which works at \( 42^\circ \text{C} \) 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 \( \text{SpO}_2 \) and Pt\( \text{CO}_2 \) at \( 42^\circ \text{C} \) was tested. The sensor was adapted to the ear of a neonate with a Vaseline (Convatec; Princeton, NJ). Data obtained from the ear sensor were compared with \( \text{SpO}_2 \) Finger/Heel, \( \text{SaO}_2 \), and \( \text{PaCO}_2 \) 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 group and 37.9 weeks (range: 29 6/7–41 0/7) in the capillary group. The postconceptional age of the patients was 3.5 days (range: 1–28) in the capillary blood sample group (\( n = 30 \)) and 6 days (range: 2–28) in the capillary blood sample group (\( n = 30 \)). Patient weight was 3.02 kg (range: 1.5–4.5) in the other group. Three patients had weights of \( <1500 \text{ g} \), whereas \( \text{SpO}_2 \) Finger/Heel values were slightly lower than \( \text{SaO}_2 \) (bias: 0.52%).

Conclusion. The TOSCA monitor with the ear sensor adapted to ears of neonates allows reliable estimation of \( \text{SaO}_2 \) and \( \text{PaCO}_2 \). 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;115:64–68. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2004-0946; noninvasive monitoring, oxygenation, pulse oximetry, carbon dioxide, neonate.

ABBREVIATIONS. \( \text{SaO}_2 \), arterial oxygen saturation; \( \text{PaCO}_2 \), partial arterial pressure of carbon dioxide; Pt\( \text{CO}_2 \), transcutaneous measurement of \( \text{PCO}_2 \).

Arterial oxygen saturation (\( \text{SaO}_2 \)) and partial arterial pressure of carbon dioxide (\( \text{PaCO}_2 \)) are 2 of the most important respiratory parameters in the treatment of critically ill neonates. Whereas \( \text{SaO}_2 \) can be estimated by means of pulse oximetry, \( \text{PaCO}_2 \) is assessed from arterial blood samples or can be estimated from central-venous or capillary blood samples. However, arterial and central catheters are invasive approaches and not always available. They represent a risk for thrombosis, infection, and iatrogenic anemia caused by repeated diagnostic blood drawing. Noninvasive monitors of \( \text{SaO}_2 \) and \( \text{PaCO}_2 \) in newborns are desirable to reduce repeated invasive blood drawing and to detect immediately respiratory deterioration.1 End-tidal \( \text{CO}_2 \) is unreliable in newborns with a large air leak around the tube or with continuous positive airway pressure masks.

Transcutaneous measurement of \( \text{PCO}_2 \) (Pt\( \text{CO}_2 \)) represents a simple and noninvasive technique for continuous monitoring of ventilation.2,3 However, sensor preparation, positioning, taping, and repeated changes of the sensor location make the handling difficult and complicates its use in the neonatal care...
unit. Recently, a new sensor for combined assessment of \( \text{SpO}_2 \) and \( \text{Ptco}_2 \) has been introduced (TOSCA Monitor; Linde Medical Sensors, Basel, Switzerland). The monitor combines pulse oximetry and \( \text{Ptco}_2 \) 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.\(^4\)\(^5\) 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 \( \text{SpO}_2 \) and \( \text{Ptco}_2 \) 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 \( \text{PCO}_2 \) sensor and the basic elements of a pulse oximeter sensor. The sensor (and also the pH electrode) was miniaturized to fit 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. The monitor displays when 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 50s and below 0.5%/hour during the 14 days, respectively.

\( \text{Ptco}_2 \) 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 program. Disposable low-pressure adhesive attachment clips for sensor placement at the ear lobe are provided. According to the manufacturer, the sensor has to be changed between the left and right ear lobes only twice a day, because the skin is warmed below the sensor.

After the automated calibration, the sensor was attached to the right ear lobe. After at least 10 minutes for equilibration, arterial or capillary blood samples were taken as required by the patient’s clinical condition and analyzed by a blood gas analyzer (ABL700; Radiometer, Copenhagen, Denmark).

Arterial blood samples were taken in 30 newborns from the arterial line (umbilical artery, radial artery, or posterior tibial artery), which was used for continuous arterial blood pressure monitoring. In patients with echocardiographic determined intracardiac right-to-left shunt or congenital heart disease, only preductal arterial blood was drawn from a right-sided radial arterial cannula, and preductal \( \text{SpO}_2 \) was measured. In 30 patients, capillary blood samples were taken from the right prewarmed heel by means of heparinized glass capillaries. All neonates with a capillary blood drawing were older than 24 hours.\(^6\) Each patient was studied only once. Patients were not selected for age, weight, or anatomy of their ears.

At the time of arterial or capillary blood sampling, the following parameters were recorded: \( \text{SpO}_2 \), \( \text{Ptco}_2 \), \( \text{Ptco}_2 \) 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.

Statistical Analysis

Data are presented as median and range. \( \text{Ptco}_2 \) TOSCA values were compared with \( \text{Paco}_2 \) and capillary \( \text{PCO}_2 \), and \( \text{SpO}_2 \) values (\( \text{SpO}_2 \) TOSCA, and \( \text{SpO}_2 \) Finger/Heel) were compared with \( \text{SaO}_2 \) using Bland Altman bias analysis. Precision was defined as 2 SD of the mean difference. Simple regression analysis was used to elucidate whether the measured parameters and the patient characteristics were significantly associated with the difference between TOSCA and invasively measured values. \( P < .05 \) was considered to indicate statistical significance.

RESULTS

The median (range) postconceptional age of the patients was 38.3 weeks (28 5/7–40 5/7) in the arterial group and 37.9 weeks (29 6/7–41 0/7) in the capillary group. Median (range) 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.
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 difference) between PtcCO2TOSCA and PaCO2 were −0.44 kPa (3.21 mm Hg) and 0.82 kPa (6.02 mm Hg) and between PtcCO2TOSCA 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, PtcCO2TOSCA 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 PtcCO2TOSCA 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. Bias and precision of PcapCO2 versus PtcCO2TOSCA values were within those reported by other investigators for capillary versus arterial PaCO2 (Table 3).

Agreement of PtcCO2TOSCA values and PaCO2 was superior to that reported in the literature for capillary PCO2 and PaCO2 (Table 3). Estimation of SaO2 with the Spo2TOSCA 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 back.

### 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>Age, d</td>
<td>3.5 (1–28)</td>
<td>9.1 (1–28)</td>
</tr>
<tr>
<td>Postconceptional age, wk</td>
<td>38.3 (28.5–40.5)</td>
<td>37.9 (29.6–41.0)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>2.02 (1.5–4.5)</td>
<td>2.76 (1–3.7)</td>
</tr>
<tr>
<td>Mean arterial pressure, mm Hg</td>
<td>44 (32–68)</td>
<td>44.5 (38–62)</td>
</tr>
<tr>
<td>Heart rate, bpm/min</td>
<td>136 (114–182)</td>
<td>140 (114–168)</td>
</tr>
<tr>
<td>pH</td>
<td>7.37 (7.2–7.54)</td>
<td>7.39 (7.26–7.47)</td>
</tr>
<tr>
<td>PaCO2, kPa/mm Hg</td>
<td>5.8 (3.3–7.8) / 42.3 (24.1–56.9)</td>
<td>–</td>
</tr>
<tr>
<td>PtcCO2TOSCA, kPa/mm Hg</td>
<td>–</td>
<td>5.77 (3.3–7.9) / 42.1 (24.1–57.7)</td>
</tr>
<tr>
<td>SaO2%</td>
<td>93.6 (64.7–98.7)</td>
<td>–</td>
</tr>
<tr>
<td>Sp02TOSCA,%</td>
<td>94 (71–100)</td>
<td>97 (84–100)</td>
</tr>
<tr>
<td>SpO2 Finger/Heel</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−PtcCO2TOSCA</td>
<td>30</td>
<td>−0.09 kPa</td>
<td>1.11 kPa</td>
<td>4.60–6.81 kPa (33.5–49.7 mm Hg)</td>
</tr>
<tr>
<td>PaCO2−PtcCO2TOSCA</td>
<td>30</td>
<td>−0.44 kPa</td>
<td>0.82 kPa</td>
<td>5.14–6.79 kPa (37.5–49.7 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 Ptcco2 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 Ptcco2 TOSCA with other Ptcco2 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 Spo2 and in particular PCO2 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 SaO2 and PaCO2 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**


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**Fig 2.** Bland and Altman bias plots for the comparison of Ptcco2 TOSCA and PaCO2. Mean difference (bias) and precision (2 SD of the mean difference) are indicated by dotted lines.

**TABLE 3.** Reference Values for the Comparison of Paco2 and Sao2 With Capillary and Transcutaneous Pco2 and Spo2 Assessment in Neoneates

<table>
<thead>
<tr>
<th>Paco2–Ptco2</th>
<th>n</th>
<th>PaCO2 vs. PtCO2 TOSCA (mmHg)</th>
<th>SaO2–Spo2</th>
<th>n</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest/abdomen 42°C</td>
<td>20</td>
<td>-0.91 kPa/-6.64 mm Hg</td>
<td>0.2%</td>
<td>54</td>
<td>Fanconi et al13</td>
</tr>
<tr>
<td>Chest/abdomen 44°C</td>
<td>20</td>
<td>-0.63 kPa/-4.6 mm Hg</td>
<td>0.66%</td>
<td>35</td>
<td>Fanconi et al13</td>
</tr>
<tr>
<td>Acute disease</td>
<td>54</td>
<td>-0.2%</td>
<td>5.0%</td>
<td>35</td>
<td>Durand and Ramanathan12</td>
</tr>
<tr>
<td>Chronic disease</td>
<td>21</td>
<td>-2.9%</td>
<td>3.6%</td>
<td>19</td>
<td>Durand and Ramanathan12</td>
</tr>
<tr>
<td>Foot/calf</td>
<td>35</td>
<td>1.44%</td>
<td>7.02%</td>
<td>35</td>
<td>Fanconi and Tschupp14</td>
</tr>
<tr>
<td>Right hand/forearm</td>
<td>19</td>
<td>0.66%</td>
<td>6.68%</td>
<td>19</td>
<td>Fanconi and Tschupp14</td>
</tr>
</tbody>
</table>


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