Evaluation of a New Combined Transcutaneous Measurement of Pco_2/Pulse Oximetry Oxygen Saturation Ear Sensor in Newborn Patients

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ABSTRACT. *Objective.* **Arterial oxygen saturation (Sao_2) and arterial carbon dioxide partial pressure ($Paco_2$) 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 Pco_2 ($Ptcco_2$) 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 (Spo_2) and $Ptcco_2$ has been introduced (TOSCA Monitor; Linde Medical Sensors, Basel, Switzerland). The monitor combines pulse oximetry and $Ptcco_2$ 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 Spo_2 and $Ptcco_2$ at 42°C was tested. The sensor was adapted to the ear of a neonate with a Varihesive layer (Conva Tec; Princeton, NJ). Data obtained from the ear sensor were compared with $Spo_{2\ Finger/Heel}$, Sao_2, and $Paco_2$ 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. Age of the newborns studied was 3.5 days (range: 1–28) in the arterial 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 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 $Ptcco_{2\ TOSCA}$ and $Paco_2$ were −0.44 kPa (−3.21 mm Hg) and 0.82 kPa (6.02 mm Hg) and between $Ptcco_{2\ TOSCA}$ and $Pcapco_2$ were −0.09 kPa (−0.67 mm Hg) and 1.11 kPa (8.07 mm Hg), respectively. Spo_2 assessment by the TOSCA revealed slightly higher values compared with Sao_2 (bias: −0.48%), whereas $Spo_{2\ Finger/Heel}$ values were slightly lower than Sao_2 (bias: 0.52%).**

Conclusion. **The TOSCA monitor with the ear sensor adapted to ears of neonates allows reliable estimation of Sao_2 and $Paco_2$. 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: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; $Paco_2$, partial arterial pressure of carbon dioxide; $Ptcco_2$, transcutaneous measurement of Pco_2.

Arterial oxygen saturation (Sao_2) and partial arterial pressure of carbon dioxide ($Paco_2$) are 2 of the most important respiratory parameters in the treatment of critically ill neonates. Whereas Sao_2 can be estimated by means of pulse oximetry, $Paco_2$ 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 Sao_2 and $Paco_2$ in newborns are desirable to reduce repeated invasive blood drawing and to detect immediately respiratory deterioration.[1] End-tidal CO_2 is unreliable in newborns with a large air leak around the tube or with continuous positive airway pressure masks.

Transcutaneous measurement of Pco_2 ($Ptcco_2$) 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

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Accepted for publication Aug 23, 2004.
doi:10.1542/peds.2004-0946
No conflict of interest declared.
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unit. Recently, a new sensor for combined assessment of Spo_2 and $Ptcco_2$ has been introduced (TOSCA Monitor; Linde Medical Sensors, Basel, Switzerland). The monitor combines pulse oximetry and $Ptcco_2$ 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 Spo_2 and $Ptcco_2$ 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 Pco_2 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. 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.

$Ptcco_2$ 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 the right ear lobe only twice a day, because the skin is warmed only to 42°C as opposed to 44°C in other sensors and only low pressure is applied to the ear lobe. Technical details and function are described in detail by Eberhard et al[4] and Dullenkopf et al.[5]

The sensor was modified in cooperation with the manufacturer for its use on the thin ear lobe of neonates with a Varihesive layer (Conva Tec, Princeton, NJ) on the reflecting side (Fig 1). This modification was necessary to compensate for the gap of 3 mm between the flanges of the clip, which was too large for the thin ear lobes of neonates.

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 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: $Spo_{2\ TOSCA}$, $Ptcco_{2\ TOSCA}$, $Spo_{2\ right\ hand\ or\ feet}$ (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. $Ptcco_{2\ TOSCA}$ values were compared with $Paco_2$ and capillary Pco_2, and Spo_2 values ($Spo_{2\ TOSCA}$ and $Spo_{2\ Finger/Heel}$) were compared with 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

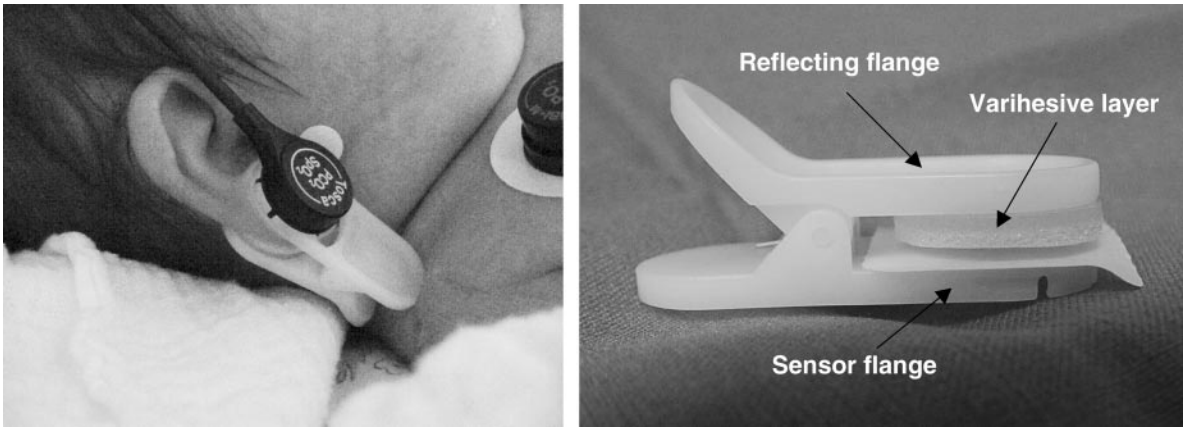

Fig 1. Disposable low-pressure adhesive attachment clip for sensor placement at the ear lobe. The clip consists of 2 clip jaws connected by a coil spring. One of the jaws to be placed at the outside of the ear lobe provides a retainer ring for inserting the sensor. This jaw also has a hole in the middle, in which a drop of contact gel has to be applied before inserting the sensor. The sensor can be rotated in the retainer ring for finding a position in which the sensor cable is not stretched or twisted. The sensor was modified in cooperation with the manufacturer for use at the thin ear lobe of neonates with a soft Varihesive layer on the reflecting side.

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

	Arterial Samples (n = 30)	Capillary Samples (n = 30)
Age, d	3.5 (1–28)	9.1 (1–28)
Postconceptional age, wk	38.3 (28 5/7–40 5/7)	37.9 (29 6/7–41 0/7)
Weight, kg	3.02 (1.5–4.5)	2.76 (1–3.71)
Mean arterial pressure, mm Hg	44 (32–68)	44.5 (38–62)
Heart rate, bpm/min	136 (114–182)	140 (114–168)
pH	7.37 (7.2–7.54)	7.39 (7.26–7.47)
$Paco_2$, kPa/mm Hg	5.8 (3.3–7.8)/42.3 (24.1–56.9)	–
$Pcapco_2$, kPa/mm Hg	–	5.77 (3.3–7.9)/42.1 (24.1–57.7)
$Ptcco_{2\ TOSCA}$, kPa/mm Hg	6.3 (3.4–9.0)/46.0 (24.8–65.7)	5.65 (3.3–8.3)/41.2 (24.1–60.6)
Sao_2, %	93.6 (64.7–98.7)	–
$Spo_{2\ TOSCA}$, %	94 (71–100)	97 (84–100)
$Spo_{2\ Finger/Heel}$	92 (68–100)	95 (82–100)

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 $Ptcco_{2\ TOSCA}$ and $Paco_2$ were −0.44 kPa (3.21 mm Hg) and 0.82 kPa (6.02 mm Hg) and between $Ptcco_{2\ TOSCA}$ and $Pcapco_2$ were −0.09 kPa (−0.67 mm Hg) and 1.11 kPa (8.07 mm Hg), respectively (Table 2, Fig 2).

Spo_2 assessment by the TOSCA revealed slightly higher values compared with Sao_2 (mean difference: −0.48%), whereas $Spo_{2\ Finger/Heel}$ values were slightly lower than Sao_2 (0.52%). Precision of $Spo_{2\ TOSCA}$ and $Spo_{2\ Finger/Heel}$ to indicate Sao_2 was similar (5.57% and 4.94%, respectively; Table 2).

DISCUSSION

In the present study, we evaluated reliability of the TOSCA monitor to reflect Sao_2 and $Paco_2$ with a single ear sensor in newborns. The main finding was a good reproducibility with clinically acceptable bias and precision between $Ptcco_2$ and Spo_2 measured at the ear lobe and invasively measured values.

Measurement of capillary Pco_2 represents a common practice to estimate $Paco_2$ in neonates without an arterial catheter with the understanding that $P_{cap}co_2$ is up to 0.5 kPa (3.7 mm Hg) higher than invasively measured $Paco_2$.[7–11] Similarly, $Ptcco_{2\ TOSCA}$ values were 0.44 kPa (3.2 mm Hg) higher than $Paco_2$ values and comparable with $P_{cap}co_2$ values in our study. In fact, comparison of $Ptcco_{2\ TOSCA}$ and $P_{cap}co_2$ values revealed a negligible bias, presumably because both measurements represent Pco_2 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 Pco_2. Bias and precision of $P_{cap}co_2$ versus $Ptcco_{2\ TOSCA}$ values were within those reported by other investigators for capillary versus arterial Pco_2 (Table 3). Agreement of $Ptcco_{2\ TOSCA}$ values and $Paco_2$ was superior to that reported in the literature for capillary Pco_2 and $Paco_2$ (Table 3). Estimation of Sao_2 with the $Spo_{2\ TOSCA}$ ear sensor revealed equal results to standard Spo_2 monitoring (Table 3).[1,14]

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 Sao_2 and $Paco_2$ 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 Spo_2 hand/foot sensor and $Ptcco_2$ 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 2. Comparison of Invasively and Noninvasively Measured Values

	n	Bias	Precision	95% Limits of Agreement
$P_{cap}co_2 - Ptcco_{2\ TOSCA}$	30	−0.09 kPa (−0.67 mm Hg)	1.11 kPa (8.07 mm Hg)	4.60–6.81kPa(33.5–49.7mmHg)
$Paco_2 - Ptcco_{2\ TOSCA}$	30	−0.44 kPa (−3.21 mm Hg)	0.82 kPa (6.02 mm Hg)	5.14–6.79kPa(37.5–49.7mmHg)
$Sao_2 - Spo_{2\ TOSCA}$	23*	−0.48%	4.94%	87.30–97.18%
$Sao_2 - Spo_{2\ Finger}$	23*	0.52%	5.57%	86.17–97.31%

In 7 children, standard Spo_2 equipment (Marquette) was not available.

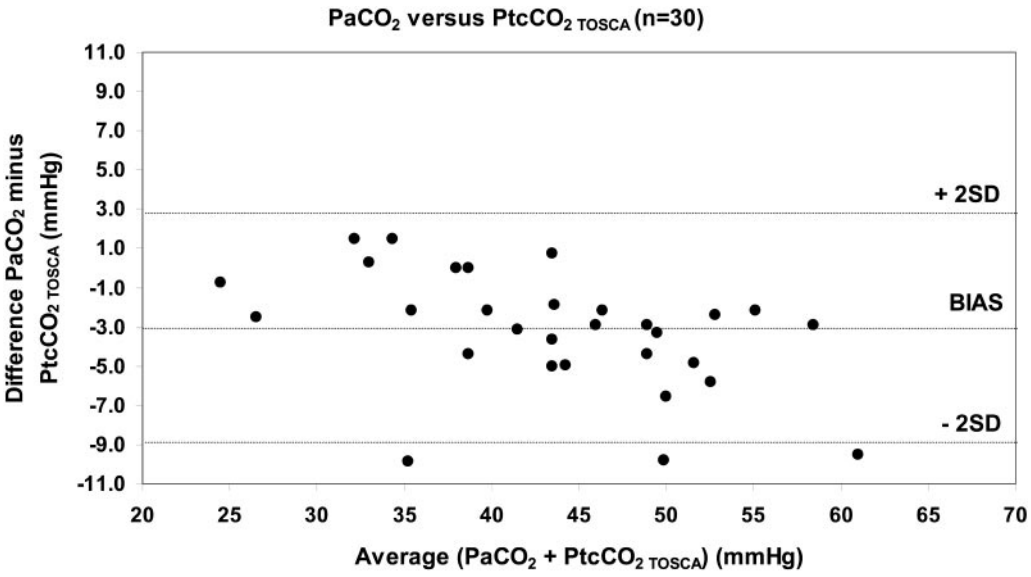

Fig 2. Bland and Altman bias plots for the comparison of $Ptcco_{2\ TOSCA}$ and $Paco_2$. Mean difference (bias) and precision (2 SD of the mean difference) are indicated by dotted lines.

TABLE 3. Reference Values for the Comparison of $Paco_2$ and Sao_2 With Capillary and Transcutaneous Pco_2 and Spo_2 Assessment in Neonates

$Paco_2 - Ptcco_2$				
Chest/abdomen 42°C	$n = 20$	−0.91 kPa/−6.64 mm Hg	1.33 kPa/9.7 mm Hg	Fanconi et al[13]
Chest/abdomen 44°C	$n = 20$	−0.63 kPa/−4.6 mm Hg	1.1 kPa/8.0 mm Hg	Fanconi et al[13]
$Sao_2 - Spo_2$				
Acute disease	$n = 54$	−0.2%	5.0%	Durand and Ramanathan[12]
Chronic disease	$n = 21$	−2.9%	3.6%	Durand and Ramanathan[12]
Foot/calf	$n = 35$	1.44%	7.02%	Fanconi and Tschupp[14]
Right hand/forearm	$n = 19$	0.66%	6.68%	Fanconi and Tschupp[14]

lap. The combination of transcutaneous oxygen saturation and $Ptcco_2$ 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 $Ptcco_{2\ TOSCA}$ with other $Ptcco_2$ 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 Spo_2 and in particular Pco_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 Sao_2 and $Paco_2$ 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.

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