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RESEARCH REPORT

Validation of a new combined transcutaneous $tcPCO_2$ and $tcPO_2$ sensor in children in the operating theater

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Abstract

Background: Arterial blood gas analysis is the gold standard for monitoring of P_aCO_2 and PaO_2 during mechanical ventilation. However, continuous measurements would be preferred. Transcutaneous sensors continuously measure blood gases diffusing from the locally heated skin. These sensors have been validated in children mostly in intensive care settings. Accuracy in children during general anesthesia is largely unknown.

Aims: We conducted a study in children undergoing general anesthesia to validate the use and to determine the accuracy of continuous transcutaneous measurements of the partial pressures of PCO_2 ($tcPCO_2$) and PO_2 ($tcPO_2$).

Methods: A prospective observational study in a tertiary care pediatric hospital in The Netherlands, from April to October 2018, in children aged 0–18 years undergoing general anesthesia. Patients were included when endotracheally intubated and provided with an arterial catheter for regular blood sampling. Patients with a gestational age <31 weeks, burn victims, and patients with skin disease were excluded. $TcPCO_2$ and $tcPO_2$ measurements were performed with a SenTec OxiVenT™ sensor (SenTec AG). Accuracy was determined with an agreement analysis between arterial and transcutaneous PCO_2 and PO_2 values, and between arterial and endtidal PCO_2 ($etCO_2$) values, according to Bland and Altman, accounting for multiple measurements per subject.

Results: We included 53 patients (median age 4.1 years, IQR 0.7–14.4 years) and retrieved 175 samples. $TcPCO_2$-P_aCO_2 agreement analysis provided a bias of 0.06 kPa (limits of agreement (LOA) −1.18 to 1.31), the $etCO_2$-P_aCO_2 agreement showed a bias of −0.31 kPa (LOA −1.38 to 0.76). Results of the $tcPO_2$-PaO_2 agreement showed a bias of 3.40 to 0.86* (mean tension) kPa.

Conclusions: This study showed good agreement between P_aCO_2 and $tcPCO_2$ in children of all ages during general anesthesia. Both transcutaneous and endtidal CO_2 measurements showed good accuracy. $TcPO_2$ is only accurate under 6 months of age.

Jan J. van Wijk and Willem van Weteringen contributed equally to this work.

KEYWORDS
carbon dioxide, hypercapnia, hypocapnia, noninvasive monitoring, transcutaneous monitoring

1 | INTRODUCTION

Blood gas monitoring during mechanical ventilation is particularly important in children. Their size and physiology make it challenging to manage their cardiorespiratory parameters during general anesthesia. Functional residual capacity is small or even absent, limiting their physiologic reserves. Children are likely to develop atelectasis, especially when higher fractions of inspired oxygen are used.[1] In addition, the developing brain is very sensitive to the vasoactive effects of carbon dioxide. Therefore, not only hyperoxia and hypoxia, but also hypocapnia and hypercapnia should be avoided in children.[2]

The gold standard for blood gas monitoring is arterial blood gas (ABG) analysis.[3] The discontinuous information provided by the intermittent withdrawal of blood poses a risk for physiologic variables that can change quickly in a patient under anesthesia. Above all, blood withdrawal in children can be time consuming and is not always possible when the patient is covered with sheets or when there is no arterial access present. Continuous, noninvasive measurements would be preferred for monitoring CO_2 and O_2 levels.

Capnography is the method most used for monitoring of CO_2.[4] During conventional ventilation, the last portion of exhaled air originates from the peripheral alveoli to which CO_2 diffuses from the alveolar blood vessels. Consequently, endtidal levels of CO_2 correspond quite well to arterial levels of CO_2. Endtidal capnography is highly dependent on the use of an endotracheal tube and is sometimes unreliable due to air leakage around the (uncuffed) endotracheal tube. This can be the case with obstructive pulmonary diseases, or in situations when no endotracheal tube is inserted at all, for example during laryngeal surgery. Pulse oximetry is the most commonly used method for continuously measuring arterial oxygenation in the operating theater.[5] Although widely used and accepted, this method has some drawbacks. In particular, it is in its common form not suitable for detecting hyperoxemia.[6]

Transcutaneous monitoring of CO_2 and O_2 has been available for decades, allowing noninvasive measurements on the skin surface.[7] The underlying method was already described in 1958 by Severinghaus and Bradley.[8] The applied sensor locally heats the skin to a few degrees above body temperature, causing skin hyperperfusion and an increase in skin metabolism. This hyperperfusion or "arterialization" leads to a local increase in skin blood supply, which increases CO_2 washout from the skin to an extent that transcutaneously measured levels correspond to blood P_aCO_2. The increase in blood flow also creates skin O_2 levels that are comparable with arterial values. The ability to measure noninvasively on the skin makes this method usable in almost all patients. Transcutaneous CO_2 and O_2 sensors have been validated for use in children but have been used mostly in neonatal and pediatric intensive care units.[9,10] Nosovitch et al.[11] were the first to show good accuracy of transcutaneous measurements of carbon dioxide compared with arterial blood gas values in children under anesthesia. This was confirmed in several studies, showing in particular that transcutaneous measurements are frequently more accurate than endtidal measurements.[12] These were often small sample size studies in a selected group of patients, such as neonates or patients with lung disease. There are still no studies with multiple samples per patient, in a population without comorbidities potentially affecting the results, that investigate accuracy in patients ranging from 0 to 18 years of age.

What is already known about the topic

Transcutaneous blood gas sensors can continuously and noninvasively estimate arterial blood gas levels.

What new information this study adds

Transcutaneous blood gas sensors provide an accurate estimation of $tcPCO_2$ during general anesthesia in children.

One of the potential limitations of transcutaneous measurements is that accuracy could be influenced by the rapid changes in hemodynamics and ventilation that can occur during surgical procedures. Inotropics and anesthetics can influence the microcirculation.[13] In addition, body temperature can vary considerably under general anesthesia. So far, the consequences of these factors on accuracy and reliability are unknown. Therefore, the aim of this validation study was to compare $tcPCO_2$ and $tcPO_2$ with arterial blood gas analysis during general anesthesia in children.

2 | METHODS

2.1 | Study setup

This was a prospective observational study. Approval for the study (MEC number MEC-2018-1102) was granted on April 17, 2018, by the local medical ethics committee (Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands) that waived the need for application of the medical research involving human subjects act (WMO). Written informed consent was obtained from all patients and/or parents.

Patients of age 0–18 years, scheduled for a procedure in the operating theaters of Erasmus MC-Sophia Children's Hospital, undergoing general anesthesia with endotracheal intubation and provided with an arterial catheter for regular blood sampling as standard

of care were eligible. Potential subjects with a gestational age of 31 weeks or less at the time of inclusion and/or patients with a skin disease or burns were excluded. Patients were included in a preset timeframe of six months.

2.2 | Study procedure

Included children were provided with a SenTec OxiVenT™ Sensor (SenTec AG) for transcutaneous monitoring of oxygen and carbon dioxide that was connected to a SenTec SDM-PO2 monitor. A drop of contact gel (SenTec GEL-04) was placed on the sensor, after which the sensor was attached to the skin with a multisite attachment ring. All children underwent general anesthesia, for which the choice of anesthetics and medication was at the discretion of the attending pediatric anesthesiologist. During all procedures, patients were mechanically ventilated and had sidestream endtidal CO_2 monitoring (Dräger Primus Infinity® Empowered, Dräger Medical AG & Co). When blood gases were drawn as part of standard care from the arterial catheter, these were analyzed immediately (Radiometer ABL800 FLEX) and corrected by the analyzer to a temperature of 37°C. The blood gas analyzer applied automated two-point and one-point calibrations in eight-hour and four-hour intervals. At the exact moment of blood gas withdrawal, the time and transcutaneous blood gas values were manually and digitally recorded on a data record form. Ventilation was not adjusted in 5 min prior to blood gas sampling. Patient's temperature was recorded automatically every minute throughout the procedure (Dräger M540, Dräger Medical AG & Co) in the electronic patient information system (HiX, ChipSoft B.V.).

2.3 | Transcutaneous device settings

All transcutaneous monitors were continuously powered on and were allowed a stabilization time of at least 45 min after application of a new sensor membrane. Membranes were changed every 4 weeks, or earlier in the case of visible damage or recurring calibration errors. Calibration was performed according to the manufacturer's guidelines. Temperature settings were applied according to hospital protocol, using a temperature of 43°C for all children and (preterm) neonates. All transcutaneous measurements were real-time corrected to a temperature of 37°C and were not corrected for measurement drift. The site time feature was enabled, lowering the sensor temperature to 39°C after a preset time interval was exceeded in order to prevent skin burns. The site time limit was set to 3 h for preterm neonates, and 4 h for term neonates and children in accordance with the hospital protocol. After elapsing of this time interval, a sensor calibration was mandatory before the measurement could be continued. After calibration, the transcutaneous sensor was placed at a different measurement site. At the end of the procedure, the sensor was removed and the measurement sites were inspected for skin abnormalities.

2.4 | Parameters and data collection

The SenTec SDM-PO2 monitor internally stored the $tcPCO_2$ and $tcPO_2$ values at a 1 Hz rate with timestamps. Transcutaneous blood gas values were exported using V-Stats software (SenTec AG). Parameters from the mechanical ventilator and patient monitor were stored automatically at a 1 Hz rate on a network data storage system, from which ventilation parameters and vital parameters could be exported. Patient characteristics were retrieved from the electronic patient information system. The patient monitor, transcutaneous monitor, and electronic patient information system were time-synchronized to an institutional time server.

2.5 | Statistical analysis

The primary study parameters in this study were $tcPCO_2$ and $tcPO_2$ values measured with the OxiVenT Sensor. These values were compared with the gold standard of blood gas analysis. To evaluate the accuracy (ie, the closeness of the measurements to the blood gas values as reference), we describe agreement between measurements using the analysis according to Bland and Altman (A-B plot), with correction for multiple measurements per subject.[14] The bias (mean difference between the reference and test method) represents the systematic error between the two methods. As a measure of precision (ie, the spread of repeated measurements), the limits of agreement were calculated as bias +1.96 SD, defining the range in which 95% of the differences between the methods are expected to reside. Subsequently, the percentage error (PE) was calculated. In the case of heteroscedasticity, in the reference samples, the method for determination of agreement of Ludbrook was applied.[15] The Bland–Altman method for showing 95% confidence limits was used. For this methodology, ordinary least squares were replaced by generalized least squares.

3 | RESULTS

Fifty-three patients were included after giving informed consent between April and October 2018, from which 175 blood samples were retrieved. Patient characteristics are listed in Table 1.

These blood samples, combined with the transcutaneous measurements, resulted in 172 data pairs for agreement of $tcPCO_2$ with P_aCO_2, 171 data pairs for agreement of $etCO_2$ with P_aCO_2 and 131 data pairs for agreement of $tcPO_2$ with PaO_2. This was the result of missing data, caused by sampling error and equipment failure. Three $etCO_2$ samples were excluded due to the absence of a capnography plateau. Sample characteristics are listed in Table 2.

Results of $tcPCO_2$-P_aCO_2 agreement analysis showed a bias of 0.06 kPa (limits of agreement −1.18 to 1.31) and $etCO_2$-P_aCO_2 agreement had a bias of −0.31 kPa (limits of agreement −1.38 to 0.76). These results are displayed in Figures 1 and 2, respectively,

TABLE 1 Patient characteristics

Patients (*n*)	53
Samples per patient	3 (3–4)
Age	4 (0–14)
Weight	17.50 (7.80–51.30)
Gender (male)	27 (50.9)
ASA classification	
I	24 (45.3)
II	15 (28.3)
III	11 (20.8)
IV	3 (5.7)
Type of surgery	
(Intra)cranial	23 (43.5)
Esophageal atresia correction	5 (9.4)
Diaphragmatic hernia correction	4 (7.5)
Spinal fusion	21 (39.6)
Sedative	
Propofol	24 (45.3)
Sevoflurane	29 (54.7)
Cuffed tube	46 (86.8)

Note: Values are expressed as median (IQR) or *n* (%).
Abbreviation: IQR; interquartile range.

TABLE 2 Sample characteristics

Samples (*n*)	175
PaO_2, kPa	24.60 (19.40–28.95)
P_aCO_2, kPa	5.1 (4.71–5.60)
FiO_2, %	38 (34–41)
Core temperature, °C	36.8 (36.4–37.2)
Ventilation mode	
Spontaneous	2 (1.1)
Pressure control	40 (22.9)
Volume control	133 (76.0)

Note: Values are expressed as median (IQR) or *n* (%).
Abbreviation: IQR; interquartile range.

using the Bland–Altman method with correction for repeated measures.

Heteroscedasticity in the PaO_2 values led to the application of a generalized least squares model with the method of Bland–Altman applied for the 95% confidence limit calculation. These confidence limits represent the accuracy of $tcPO_2$ with PaO_2 as a reference. Over all 131 samples, there was a bias of 3.40–0.86* (mean tension), an upper limit of agreement of 6.06–0.36* (mean tension), and a lower limit of agreement of 0.74–1.36* (mean tension) kPa, which are graphically shown in Figure 3.

There was a clear effect of age on measurement accuracy of $tcPO_2$. In children under the age of 6 months, agreement of the available 18 samples showed a bias of −1.43 kPa (limits of agreement −6.27 to 3.42). In children older than 6 months, heteroscedasticity in the mean PaO_2 values resulted in markedly wider limits over the mean tension, and was therefore not comparable with the traditional agreement analysis. The two age groups are shown in Figure 3.

Body temperature was within the normal range. Hemodynamic support was facilitated in 32 patients with low-dose phenylephrine or noradrenaline, often combined with dobutamine. No cases of hypoperfusion or shock were occurred. No adverse events due to skin heating at the sensor attachment site were noticed.

4 | DISCUSSION

Our results demonstrate an excellent agreement between $tcPCO_2$ and P_aCO_2 in children of all ages during general anesthesia. Both transcutaneous and endtidal CO_2 measurements showed excellent accuracy. Oxygen measurements are accurate only in infants up to approximately 6 months of age.

There is only a small number of prospective observational validation studies on transcutaneous blood gas measurements in anesthetized children.[12,16,17] This study aimed to investigate the accuracy and reliability of transcutaneous blood gas measurements in the pediatric operating theater. Although mostly applied in neonates and infants, transcutaneous blood gas measurements are potentially very useful for monitoring in older children. Based on the studies in adults, it is likely that these sensors are applicable in older children as well. Although skin maturation is complete at approximately one year of age,[18] other factors such as blood pressure change over the following years, potentially affecting measurement accuracy.[19,20] Data were collected prospectively, ensuring precisely time-synchronized data collection. No adverse events related to transcutaneous monitoring, such as skin burns, were occurred.

Measurement drift is one of the main reasons for transcutaneous measurement values to deviate from arterial blood gas values.[21] Although postcorrection for drift is possible by calibrating before and after the measurement, drift-corrected values are not available during measurements. During relatively short procedures, drift is unlikely to cause clinically relevant inaccuracy. Reduction or removal of $tcPCO_2$ drift would, however, benefit the reliability of these measurements.

The software implementation of the investigated transcutaneous monitor was aimed at the intensive care setting, indicating validity of a measurement based on blood gas level variation over time. As a consequence, the dynamic situations in respiration that occur in the operating theater were often indicated to be invalid. Device settings for use in the operating theater would be favorable.

There are some physiologic limitations of transcutaneous measurements as well. The device needs a skin arterialization time of up to fourteen minutes.[22] The sensor should therefore ideally be placed well before induction, but this can be challenging in an

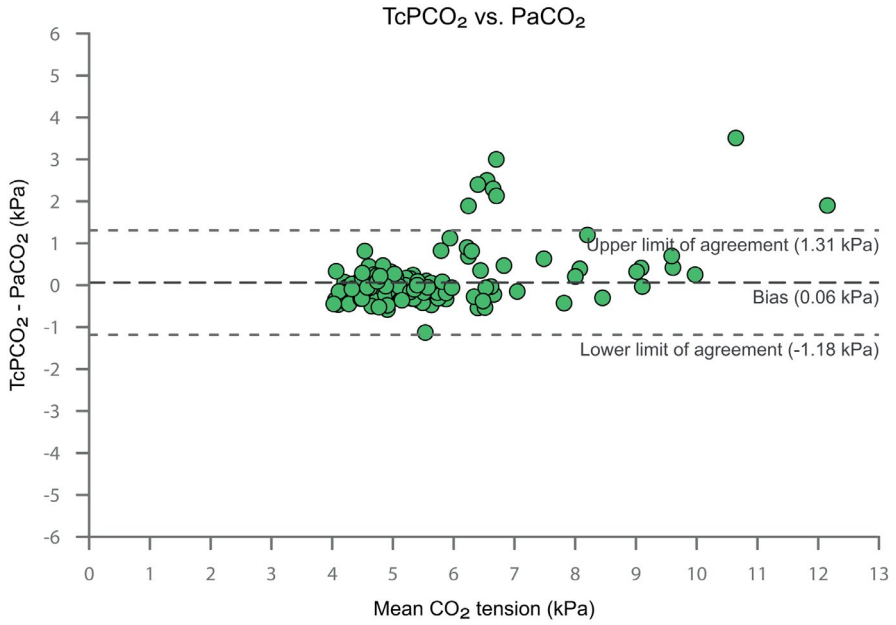

FIGURE 1 Bland–Altman plot of the agreement of $tcPCO_2$ with P_aCO_2

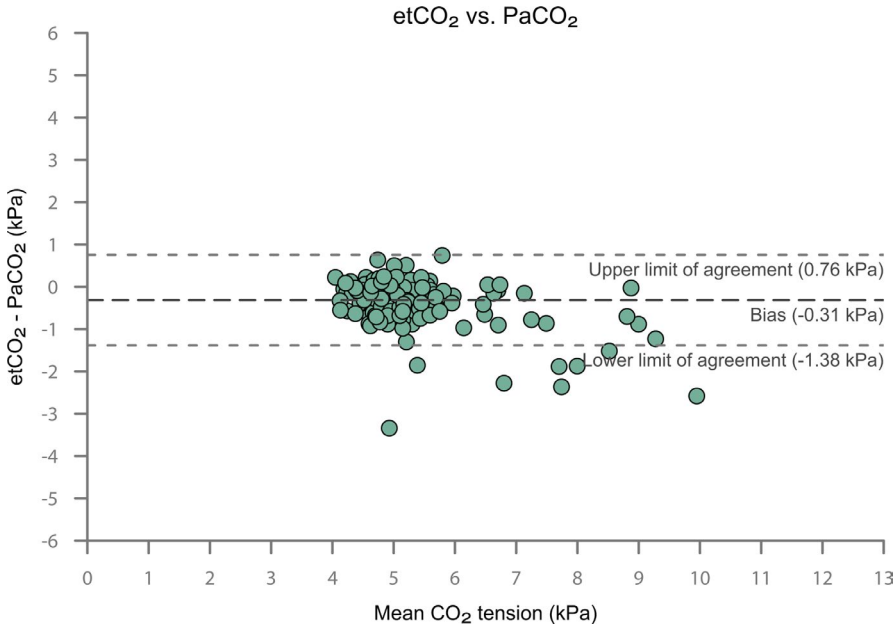

FIGURE 2 Bland–Altman plot of the agreement of $etCO_2$ with P_aCO_2

awake child. When the temperature is set to 43°C, the measurement site should be changed every three to four hours because heating of the skin leads to a limited risk of burns. Protocols for clinical skin assessment and sensor position alteration have eliminated this risk in clinical practice. However, calibrations during long procedures result in a period without transcutaneous measurements. Calibration-free sensors would allow the continuous availability of these measurements.

The sample size of this study does not permit detailed subgroup analyses. There could be a selection bias due to the fact that children under general anesthesia will only get an arterial catheter when hemodynamic instability is expected. This instability could impact skin perfusion, and with it sensor accuracy. The occurrence of hemodynamic changes depends highly on the type of surgery, the estimated volume shifts, and expected blood loss. As a result, there was a limited range in the included types of procedures. There was also a limited use of inotropics and no case of hypoperfusion or shock. Therefore, no information was obtained on situations in which severe hemodynamic disturbances are present. All children were mechanically ventilated that allowed tight control of carbon dioxide levels, leading to a narrow range in measured values.

Even though these devices are available and certified, we wanted to investigate their reliability and safety, and therefore their usability in clinical decision making. Transcutaneous sensors are commercially available and, although skin arterialization time is still needed, thanks to modern technology easy to use in a dynamic operating theater environment. The risk of burns has practically been eliminated due to accurate temperature control and strict clinical protocols.

We have provided evidence for the accuracy of transcutaneous monitors during pediatric anesthesia. Future research and

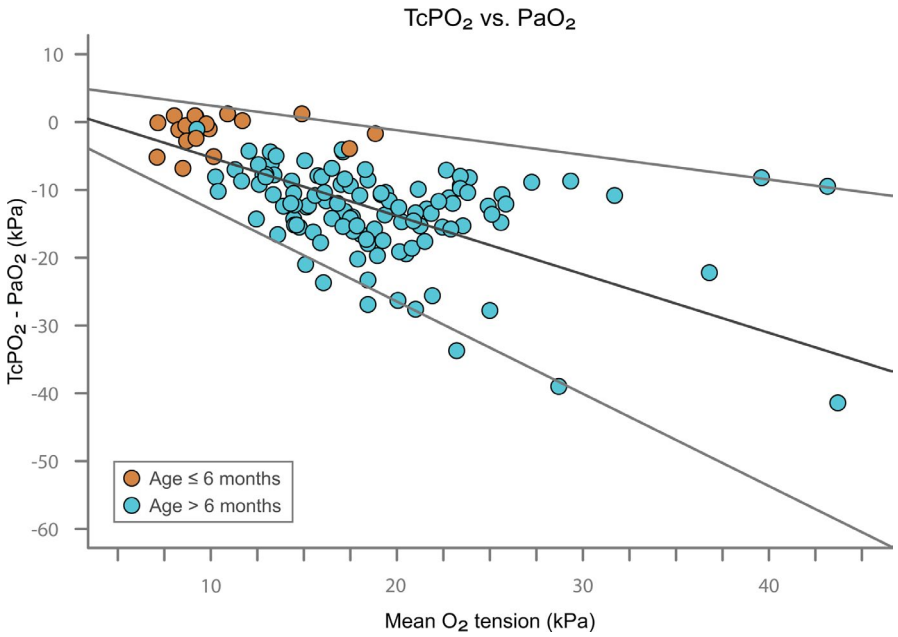

FIGURE 3 Accuracy of $tcPO_2$ with PaO_2 as reference, with median and limits of agreement taking heteroscedasticity of the data into account for all samples. Subgroups are shown for ages ≤6 months and >6 months

developments should address the application of transcutaneous measurements in pediatric anesthesiology to improve the usability of the device, aiding in the acceptance of the technology. We suggest new studies in areas where these devices can be of clinical significance, for instance in surgical procedures with challenging respiratory conditions, hemodynamic instability, and commonly unmonitored procedures such as laryngeal surgery.

5 | CONCLUSION

Validation of carbon dioxide measurements showed an excellent agreement between $tcPCO_2$ and P_aCO_2 in children of all ages during general anesthesia. Both transcutaneous and endtidal CO_2 measurements show excellent accuracy. Transcutaneous oxygen measurements are accurate in children under 6 months of age.

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CONFLICTS OF INTEREST

S.E Hoeks is a statistics editor of the Editorial Board of Pediatric Anesthesia.

AUTHOR CONTRIBUTIONS

J.J. van Wijk, MD and W. van Weteringen, MD were involved in study design, data collection, data analysis, and writing of manuscript. S.E. Hoeks, PhD was involved in study design, and data analysis. L.M. Staals, MD, PhD was involved in study design, data analysis, and writing of manuscript.

ETHICAL APPROVAL

This study complies with the current ethical laws in The Netherlands and is conducted according to the principles of the Declaration of Helsinki (2013). The local medical ethics committee waived the need for application for medical research involving human subjects act (WMO), due to the observational study design and because patients were not subjected to interventions.

DATA AVAILABILITY STATEMENT

The study data are not publicly available due to institutional policy. Data are available upon reasonable request from the corresponding author.

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