Clinical validation of a digital transcutaneous PCO2/SpO2 ear sensor in adult patients after cardiac surgery

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Abstract: Objective: The aim of this study was to validate the V-Sign digital sensor (SenTec AG, Therweil, Switzerland) for combined noninvasive assessment of pulse oxymetric oxygen saturation (SpO2) and transcutaneous carbon dioxide tension (PtcCO2) in adults after cardiac surgery. Methods: In twenty one patients, aged 51-86years, simultaneous measurements of blood gases with the V-Sign Sensor and with two Nellcor Durasensors (model DS-100A), one at the opposite earlobe and one with a finger clip, were compared first during hyper-, normo- and hypocapnia and at different pulse rates using a pacemaker, and then at 2-h intervals up to 8h. Agreement was assessed by Bland-Altman analysis. Results: PtcCO2 data of three patients were excluded because of calibration failure of the device. Median (range) PtcCO2 for the remaining patients was 5.49 (3.3-7.6) kPa and arterial carbon dioxide tension (PaCO2) was 5.43 (3.61-7.41) kPa. Corresponding mean bias was +0.05kPa and limits of agreement (LOA) were −1.2/+1.3kPa. During normo- and hypoventilation, mean bias was good at +0.02 and +0.04kPa respectively, but limits of agreement were poor at −0.67/+0.69 and −0.81/+0.88kPa. In 10 patients, an initial overshoot of PtcCO2 was observed. Mean bias of SpO2 and pulse rate was close to zero (−1.5% and +0.001bpm respectively), but limits of agreement were unacceptably high (−21.4/+18.4% and −22.3/+22.3bpm). Conclusions: In the present state of development the SenTeC Digital monitor V-Sign device has serious limitations. Additional efforts are necessary to eliminate calibration failures and the initial overshoot of PtcCO2 as well as to improve detection of SpO2 and pulse rate

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CLINICAL VALIDATION OF A DIGITAL TRANSCUTANEOUS PCO_2/SPO_2 EAR SENSOR IN ADULT PATIENTS AFTER CARDIAC SURGERY

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ABSTRACT. Objective. The aim of this study was to validate the V-Sign digital sensor (SenTec AG, Therweil, Switzerland) for combined noninvasive assessment of pulse oxymetric oxygen saturation (SpO_2) and transcutaneous carbon dioxide tension ($PtcCO_2$) in adults after cardiac surgery. **Methods.** In twenty one patients, aged 51–86 years, simultaneous measurements of blood gases with the V-Sign Sensor and with two Nellcor Durasensors (model DS-100A), one at the opposite earlobe and one with a finger clip, were compared first during hyper-, normo- and hypocapnia and at different pulse rates using a pacemaker, and then at 2-h intervals up to 8 h. Agreement was assessed by Bland-Altman analysis. **Results.** $PtcCO_2$ data of three patients were excluded because of calibration failure of the device. Median (range) $PtcCO_2$ for the remaining patients was 5.49 (3.3–7.6) kPa and arterial carbon dioxide tension ($PaCO_2$) was 5.43 (3.61–7.41) kPa. Corresponding mean bias was +0.05 kPa and limits of agreement (LOA) were −1.2/+1.3 kPa. During normo- and hypoventilation, mean bias was good at +0.02 and +0.04 kPa respectively, but limits of agreement were poor at −0.67/+0.69 and −0.81/+0.88 kPa. In 10 patients, an initial overshoot of $PtcCO_2$ was observed. Mean bias of SpO_2 and pulse rate was close to zero (−1.5% and +0.001 bpm respectively), but limits of agreement were unacceptably high (−21.4/+18.4% and −22.3/+22.3 bpm). **Conclusions.** In the present state of development the SenTeC Digital monitor V-Sign device has serious limitations. Additional efforts are necessary to eliminate calibration failures and the initial overshoot of $PtcCO_2$ as well as to improve detection of SpO_2 and pulse rate.

KEY WORDS. combined transcutaneous PCO_2 and SpO_2, digital ear sensor, cardiac surgery intensive care unit.

ABBREVIATIONS

bt	blood temperature
CI	cardiac index
ICU	intensive care unit
N395-ECG	pulse rate measured by Nellcor N-395 using an ear-lobe senor
N395-SpO_2	partial oxygen saturation measured by Nellcor N-395 using an ear-lobe sensor
N595-ECG	pulse rate measured by Nellcor N-595, using a finger clip
N595-SpO_2	partial oxygen saturation measured by Nellcor N-595 using a finger clip
PaO_2	arterial oxygen tension
$PaCO_2$	arterial carbon dioxide tension

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pCO_2	partial carbon dioxide tension
P_ECO_2	endtidal carbon dioxide partial pressure
PR	pulse rate
SaO_2	arterial oxygen saturation
SDM-PR	SenTec Digital Monitor pulse rate
SDM-SpO_2	SenTec Digital Monitor pulse oximetry oxygen saturation
SpO_2	pulse oximetry oxygen saturation
$TcPCO_2$	transcutaneous partial carbon dioxide tension
TOSCA	TOSCA monitor, Linde Medical Sensors, Basel Switzerland for combined measurement of transcutaneous partial carbon dioxide tension, pulse oximetry oxygen saturation
V-Sign™	V-Sign™ ear-lobe sensor (SenTec Digital Monitor System (SDM))

INTRODUCTION

Continuous non-invasive monitoring of respiratory parameters is desirable under a variety of circumstances. The use of oxygen saturation as measured by pulse oximetry (SpO_2) and capnometric assessment of end-tidal carbon dioxide partial pressure ($PECO_2$) is standard practice for non-invasive monitoring of oxygenation and ventilation during anaesthesia. However, during cardiothoracic or laparoscopic surgery and in patients with pulmonary disease, $PECO_2$ is not always accurate [1–4]. In spontaneously breathing patients, correct assessment of $PECO_2$ is difficult [5]. Acute changes in ventilation are first reflected by changes in partial pressure of CO_2 (PCO_2), whereas the change in oxygenation detected by SpO_2, is delayed. In newborns and infants, transcutaneous measurement of carbon dioxide partial pressure ($PtcCO_2$) was introduced 20 years ago [6–8] for noninvasive continuous monitoring of ventilation. However, sensor preparation, positioning, taping, and the necessity for repeated changes of the sensor's location made handling difficult and complicated its use [9]. More recently, two new devices, the SenTec Digital Monitor V-sign sensor and the TOSCA devise, for combined assessment of $PtcCO_2$ and SpO_2 using a single ear-clip sensor were introduced [9–12]. To the best of our knowledge, only three studies assessing the accuracy and reliability of the V-Sign sensor (V-Sign Sensor, SenTec Digital Monitoring System: SenTec AG, Therwil, Switzerland) have so far been published: one in adult volunteers [11], one in patients during bronchoscopy [12], and one in critically ill patients in a medical intensive care unit (ICU) [13]. The V-Sign sensor measures $PtcCO_2$, pulse rate and SpO_2 continuously and noninvasively. It combines the elements of a Stow-Severinghaus-type PCO_2 sensor and a conventional pulse oximetry sensor. The sensor temperature is heated up to 42°C to achieve local arterialization of the skin at the site for $PtcCO_2$ monitoring. Prior to the application of the sensor to the patient's ear, an automatic calibration of the sensor is performed in vitro. Afterwards, the sensor is mounted at the ear lobe, and the first measurement is done after allowing a 20-min equilibration time. Until now, no data were available regarding the accuracy and reliability of this device in critically ill adult patients after cardiac surgery

The aims of this study were (i) to validate the data acquired with the V-Sign sensor in comparison with arterial carbon dioxide tension ($PaCO_2$), arterial oxygen saturation (SaO_2), and pulse rate derived from the electrocardiography under various clinical conditions in patients early after cardiac surgery, (ii) to assess the agreement of SpO_2 and pulse rate with corresponding data monitored with standard ear-clip and finger-clip pulse oximetry devices, and (iii) to investigate the safety and feasibility of the V-Sign device.

METHODS AND MATERIALS

With ethics committee approval and written informed consent, 21 patients scheduled for elective cardiac surgery were enrolled in this prospective single-center trial. Exclusion criteria were non-German-speaking patients, unstable haemodynamics, arrhythmias, and age <18 years. Criteria for ending a subject's participation were unstable haemodynamics and/or significant arrhythmias, need for re-operation, a serious skin lesion at the earlobe and withdrawal of consent by the patient or relatives. Before the surgery, standard instrumentation included a 2-channel ECG (leads II and V_5) (Hellige SMU 612 monitor, Marquette-Hellige, Freiburg i.Br, Germany), continuous arterial blood pressure monitoring via a fluid-filled catheter system (Baxter Healthcare Corp. Cardiovascular Group Irvine) connected to the nondominant radial artery, a triple-lumen central venous catheter (Arrow International, Reading, PA) and a 7.5-FG thermistor-tipped, flow-directed pulmonary artery catheter (Intelli-Cath Baxter Healthcare Corporation Edwards Critical Care Division), introduced through an 8.5-FG introducer (Arrow International) inserted in the right internal jugular vein and connected to a cardiac output computer system (9520A Baxter Healthcare Corporation).

According to institutional policy, all patients were instrumented with right atrial and right ventricular epicardial pacemaker wires before chest closing. After arrival of the patient in the ICU, three pulse oximeter sensors

were attached according to the manufacturer's directions. For noninvasive, continuous recording of SpO_2, $PtcCO_2$ and pulse rate, the V-Sign sensor was attached to the inside of the left ear lobe using an adhesive Ear-Clip, and connected to the SenTec Digital Monitor. A second sensor for noninvasive, continuous recording of SpO_2 (Nellcor Durasensor model DS-100A) was attached to the inside of the right earlobe and connected to a Nellcor N-395 pulse oximeter (Nellcor Puritan Bennet Inc., Pleasanton, CA). Another Nellcor Durasensor (model DS-100A) was attached by finger clip and connected to a Nellcor N-595 pulse oximeter. Data were computed for subsequent plotting and statistical analysis. Arterial blood samples were drawn from the indwelling arterial catheter at time points specified in the study protocol (see below). $PaCO_2$ was measured at a standard temperature of 37°C, and SaO_2 was determined by direct oximetry (multi-wavelength hemoximetry) (ABL 625/620, Radiometer Medical A/S, Akandevej 21 DK-2700 Bronshoj, Denmark).

All data detected by the V-sign sensor, and by the ear-clip and finger-clip sensors of the Nellcor devices were automatically collected online by a computing system. The time points of the arterial samples and the results of the corresponding blood gas and haemoximetry values were also recorded.

At the time points of the arterial blood samples, all data were documented on a separate protocol sheet. Additional recordings included $PECO_2$, mean arterial pressure, cardiac index, blood temperature, peripheral skin perfusion (I = warm and dry; II = cool; III = cold) and skin status at the earlobe where the V-sign sensor was attached (0 = no reddening; 1 = slight reddening; 2 = reddening; 3 = intensive reddening; 4 = blister). After haemodynamic stabilization in the ICU, arterial blood samples (BS) were taken before attaching the sensors (BS1), 7.5 min (BS2) and 15 min (BS3) after attaching the sensors (calibration procedure); two samples were taken with an interval of 5 min after 20 min of hyperventilation (target $PaCO_2$ = 4.5 kPa) (BS4 and BS5); two samples were taken with an interval of 5 min after 20 min of normoventilation (target $PaCO_2$ = 5.0 kPa) (BS6 and BS7), two samples were taken with an interval of 5 min after 20 min of hypoventilation (target $PaCO_2$ = 6.5 kPa) (BS8 and BS9), and two samples were taken with an interval of 5 min after 2, 4, 6 and 8 h after starting the trial (BS10-BS17). To investigate the accuracy of the V-Sign device to detect pulse rate, we varied the heart rate, each for a duration of 30 s, from 60 to 90 to 120 bpm, using an external temporary pacemaker during the period between the blood samples BS9 and BS10. Before starting the trial and after 2, 4, 6, 8 and 14 h, the skin status at the earlobe was documented.

The power calculation revealed that 20 patients were necessary to estimate variation between and within subjects with an accuracy of at least 15%. Bland-Altman analysis [14] was applied to assess mean bias and limits of agreement (LOA) (±2 SD of bias) of $PaCO_2$ and $PtcCO_2$, SaO_2 and corresponding values of V-Sign SpO_2, Nellcor N-395 SpO_2 and Nellcor N-595 SpO_2 as well as pulse rate derived from the ECG, V-Sign, Nellcor N-395 and Nellcor N-595. Multiple regression analysis was performed to assess whether blood temperature, pulse rate, cardiac index, skin status and mean arterial pressure significantly influenced $PtcCO_2$, $PaCO_2$ and the difference between $PtcCO_2$ and $PaCO_2$ ($PtcCO_2$–$PaCO_2$). In addition, linear regression analysis was performed to assess first differences in transcutaneous and arterial PCO_2.

RESULTS

About 21 patients were enrolled; their characteristics and cardiorespiratory parameters are listed in Table 1. $PtcCO_2$ values for 3 patients were excluded because of calibration failure of the V-Sign device. In the remaining 18 patients, 273 data pairs of $PtcCO_2$ and $PaCO_2$ were available for analysis. Median (range) $PtcCO_2$ and $PaCO_2$ were 5.49 (3.3–7.6) and 5.43 (3.61–7.41) kPa, respectively. Corresponding mean bias was +0.05 kPa and LOA were −1.2/+1.3 kPa (Figure 1, Table 2**)**. In 10 patients, $PtcCO_2$ showed an initial overshoot until 8–25 min following calibration of the system (Figure 2). At the 2- to 8-h sample times, $PtcCO_2$ showed a drift toward lower values when compared with $PaCO_2$ in 15 patients (Figure 2). No correlation was found between $PtcCO_2$ and $PaCO_2$ with blood temperature, pulse rate, cardiac index, skin status or mean arterial pressure, whereas the difference between $PtcCO_2$ and $PaCO_2$ significantly decreased with increasing blood temperature ($p < 0.0001$). $PECO_2$ cor-

Table 1. Patients characteristics and hemodynamic data[a]

No. of Patients	21
Age, year	69 ± 8.8 (51–86)
Male/female	16/5
BMI, kg/m^2	28.6 ± 4.7 (21.5–38.3)
Type of surgery	
CABG	11
Valve	5
Combined	5
Cardiac index, liter/min/m^2	2.66 ± 0.59 (1.53–5.18)
Mean arterial pressure, mmHg	72 ± 9 (49–105)

[a]Values are expressed as mean ± SD (range).Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft.

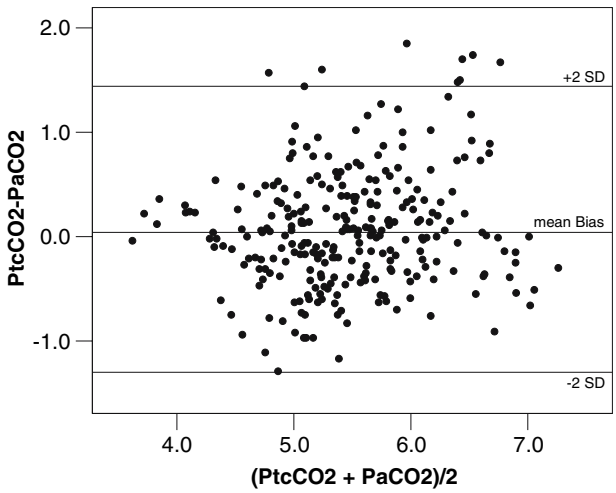

Fig. 1. Agreement between $PtcCO_2$ and $PaCO_2$ of 273 data pairs. Mean bias +0.05 kPa; limits of agreement (LOA) −1.2/+1.3 kPa.

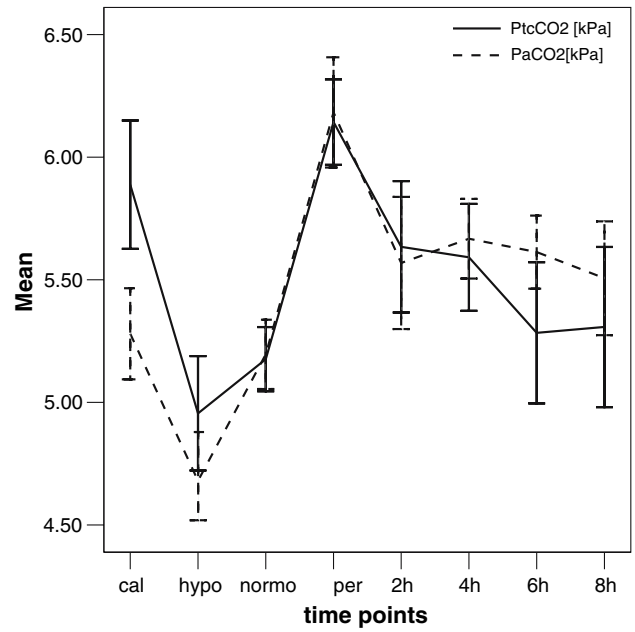

Fig. 2. $PtcCO_2$ (solid line) and $PaCO_2$ (dotted line) after calibration (cal), during hypocapnia (hypo), normocapnia (normo), and hypercapnia (hyper), and after 2 h, 4 h, 6 h and 8 h. Error bars: 95% confidence interval. $PtcCO_2$ shows an initial overshoot after calibration and a drift toward lower values arising at the 4th hour of the study period.

related well with $PaCO_2$ ($r^2 = 0.58$; $p < 0.001$), but only moderately with $PtcCO_2$ ($r^2 = 0.22$; $p < 0.0001$). Median and range of carbon dioxide tension during various respiratory conditions are listed in Table 2. During the periods of normo- and hypoventilation, $PtcCO_2$ values showed a satisfactory agreement with $PaCO_2$; agreement was less during hyperventilation (Table 3). First differences of $PtcCO_2$ and $PaCO_2$ showed only moderate correlation (Figure 3) with sensitivity of 82.9% and specificity of 54%.

Mean bias between V-Sign SpO_2 and SaO_2, and between V-Sign pulse rate and ECG-derived pulse rate was close to zero (−1.5% and +0.001 bpm, respectively), but limits of agreement were unacceptably high (−21.4/+18.4% and −22.3/+22.3 bpm). The best agreement was found between transcutaneously measured values of the Nellcor N-595 using a finger clip with SaO_2 and ECG-derived pulse rate (mean bias −0.07 % and −0.2 bpm; limits of agreement −3.6/+3.4 % and −10.7/+11.1 bpm [Table 2]). No patient showed any skin lesion or irritation up to 6 h after removal of the sensor.

Table 2. Agreement between values of non-invasive measurements (V-sign, N-395 and N-595) and those of invasive measurements, using Bland-Altman analysis

	n	Mean bias	LOA
$PtcCO_2$–$PaCO_2$, kPa	273	+0.05	−1.2/+1.3
V-Sign SpO_2–SaO_2, %	327	−1.5	−21.4/+18.4
N-395 SpO_2–SaO_2, %	297	−2.8	−19/+13.4
N-595 SpO_2–SaO_2, %	309	−0.07	−3.6/+3.4
V-Sign PR – ECG, bpm	362	+0.001	−22.3/+22.3
N-395 PR – ECG, bpm	309	+0.56	−21.9/+33.2
N-595 PR – ECG, bpm	335	+0.17	−10.7/+11.1

Abbreviations: LOA, limits of agreement; $PtcCO_2$, transcutaneous carbon dioxide tension; $PaCO_2$, arterial carbon dioxide tension; V-Sign SpO_2, oxygen saturation measured with V-sign ear sensor; SaO_2, arterial oxygen saturation; N-395 SpO_2, oxygen saturation measured with the ear sensor of Nellcor N-395 pulse oximeter; N-595 SpO_2, oxygen saturation measured with the finger clip sensor of Nellcor N-595 pulse oximeter; V-Sign PR, pulse rate measured with V-sign ear sensor; ECG, electrocardiography; N-395 PR, pulse rate measured with the ear sensor of Nellcor N-395 pulse oximeter; N-595 PR, pulse rate measured with the finger clip sensor of Nellcor N-595 pulse oximeter.

Table 3. Agreement between $PtcCO_2$ and $PaCO_2$ during various states of ventilation using linear regression (r^2) and Bland-Altman analysis

State	n	r^2	Mean bias (kPa)	LOA (kPa)
Hypoventilation	36	0.59	+0.04	−0.81/+0.88
Hyperventilation	35	0.48	+0.28	−0.98/+1.54
Normoventilation	36	0.41	+0.02	−0.67/+0.69

Abbreviations: LOA, limits of agreement.

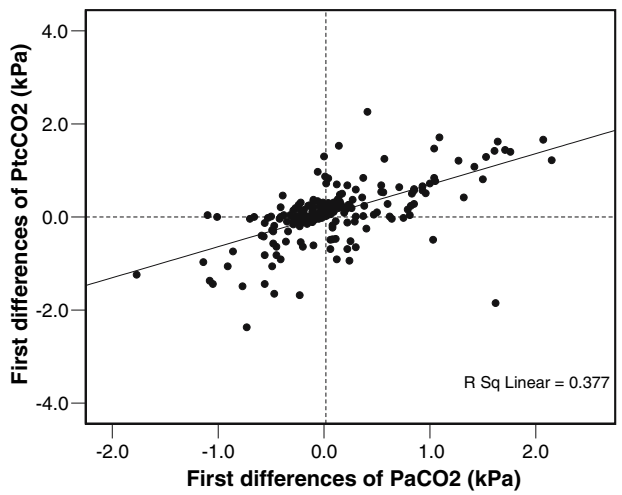

Fig. 3. First differences of $PtcCO_2$ and $PaCO_2$ ($R^2 = 0.377$, $p < 0.001$).

DISCUSSION

The main results of this study are (i) the accuracy of all $PtcCO_2$ values taken together was good, but the limits of agreement were unacceptably high; (ii) first differences of $PtcCO_2$ and $PaCO_2$ values were only moderately correlated; (iii) the best agreement of $PtcCO_2$ and $PaCO_2$ was found during normo- and hypoventilation; (iv) in the majority of patients, an initial overshoot and/or a drift to lower $PtcCO_2$ values were observed, and calibration failure of the V-Sign sensor occurred in 3 of 21 patients; (v) SpO_2 and pulse rate detection was poor.

Combined $PtcCO_2$ and SpO_2 monitors are noninvasive devices using a single sensor mounted at the earlobe. Rohling and Biro [15] investigated the Kontron device (Kontron Monitor 7840 Kontron Instruments Medical Sensors, Basel, Switzerland) in anaesthetized adult patients and found good agreement between $PtcCO_2$ and $PaCO_2$ (mean bias −0.08 kPa; limits of agreement −0.38/+0.22 kPa), and SpO_2 values differed less than 1% from those obtained by standard pulse oximetry. Dullenkopf et al. [10] and Bernet-Buettiker et al. [9] validated the TOSCA system (Linde Medical Sensors, Basel, Switzerland) in children and neonates, respectively. Both authors reported a good agreement between $PtcCO_2$ and $PaCO_2$, although their reported bias values differed significantly (−0.04 and +0.44, respectively). Whether this might be explained by the different patient populations is unclear. To our knowledge, only two reports validating the V-Sign sensor against $PaCO_2$ have so far been published [11, 13]. Kocher and coworkers [11] investigated the V-Sign sensor in six adult volunteers during hypo- and hyperventilation and reported excellent agreement between $PtcCO_2$ and $PaCO_2$ (mean bias −0.024 kPa; limits of agreement −0.31/+0.25 kPa). Recently, Rodriguez et al. [13] tested the V-Sign sensor in 50 critically ill adult patients in a medical ICU. They excluded 21% of paired PCO_2 measurements; mean bias and limits of agreement of the remaining PCO_2 data pairs were −0.03 and −1.25/+1.2 kPa, respectively.

The results of the present study correspond nicely to those of Rodriguez et al. [13] in critically ill patients. However, our data, as well as those of Rodriguez et al. showed twofold to threefold-higher limits of agreement as compared with the results of previous investigators [9–11, 15]. This difference might be explained in part by the fact that we and Rodriguez et al. performed the investigations in critically ill patients, whereas the other studies were conducted in healthy volunteers [11], in ASA I/II adult patients undergoing general anaesthesia [15] and in paediatric patient populations [9, 10]. To what extent differences in technical performance of the devices might have contributed is unclear.

Using the SenTec V-Sign device, we observed two technical problems with regard to the $PtcCO_2$ signal, an initial overshoot in 10 of our 18 patients, and a downward drift with time in 15 patients (Figure 2). An initial overshoot of the $PtcCO_2$ signal was previously reported by Kagawa and coworkers [16] using the TOSCA device and an ear probe heated to 42°C in patients during abdominal or thoracic surgery, 5–11 min after mounting the clip at the ear. The observed difference between $PtcCO_2$ and $PaCO_2$ disappeared after 25 min. In two volunteers, an initial heating of the ear sensor to 45°C for the first 15 min and then a decrease to 42°C prevented the overshoot and provided valid $PtcCO_2$ values [16]. In blood as well as in tissues, the temperature coefficient of dissolved CO_2 is 4.7% per degree centigrade. Like all other $PtcCO_2$ electrodes, the SenTec Digital Monitor V-Sign sensor corrects for this temperature coefficient as well as for an assumed diffusion gradient between epithelia and capillaries within the skin and for the locally increased metabolic rate. Normally, skin PCO_2 is a function of blood flow and metabolic rate and may be much higher than $PaCO_2$ when measured at 37°C [17]. Early after

cardiac surgery, mild residual hypothermia combined with artificial heating of the earlobe may mobilize high tissue CO_2 that has accumulated before vasodilatation occurs. Whether a short initial period of higher heating temperature of the ear sensor may eliminate the overshoot, as described by Kagawa and coworkers [16], needs further investigation.

Looking at the different time periods of the $PtcCO_2$ data acquisition, we found a drift of the initial calibration value, the extent of which differed considerably between patients, from 0.04 to 0.13 kPa/h. Although Rodriguez et al. [13], using the same device, reported a good agreement between $PtcCO_2$ and $PaCO_2$, the limits of agreement they published were similar to ours. One cannot exclude the possibility that they failed to recognize this drifting problem. With other devices, lower limits of agreement were reported [9, 10, 15]. Whether this might be due to the absence of a $PtcCO_2$ drift is unclear.

Similar to the observations of Kocher et al. [11] in six volunteers, the data we obtained during normo- and hypoventilation showed excellent accuracy of $PtcCO_2$ monitoring and acceptable limits of agreement. The agreement was less during hyperventilation, indicating a detection problem at lower PCO_2 values, which is unexplained by the observed phenomena of overshoot and drift.

Surprisingly, $PtcCO_2$ did not correlate with cardiac index values ranging between 1.5 and 5.2 liter/min/m^2. This lack of correlation, however, should be interpreted with caution, because cardiac index was within normal range for a patient population aged between 51 and 86 years of age. There were no signs of hypoperfusion associated with organ dysfunction or metabolic disturbances. The decreasing difference between $PtcCO_2$ and $PaCO_2$ with increasing body temperature can be explained by an improvement of peripheral perfusion at higher body temperatures.

$PECO_2$ correlated well with $PaCO_2$, but only moderately well with $PtcCO_2$, indicating that the $PtcCO_2$ measured with the V-Sign sensor cannot be used as a surrogate of $PECO_2$.

Regarding pulse rate and SpO_2, we observed better robustness and fewer detection disturbances using the V-Sign sensor as compared with the other devices, as indicated by a higher detection rate (Table 2). Although the detection of SpO_2 and pulse rate was significantly better with the V-Sign sensor, the limits of agreement were unacceptably high. In contrast, Kocher and investigators [11] reported that both the Nellcor N-395 earlobe sensor and the V-Sign sensor accurately tracked SpO_2 and pulse rate. However, their investigation was performed in volunteers with presumably constant body temperature, whereas our patients presented with initial hypothermia, and their blood temperature increased with time. This explanation is supported by the observation that the differences between $PtcCO_2$ and $PaCO_2$ decreased at higher body temperature. Interestingly, an excellent bias and very low limits of agreement of SpO_2 and SaO_2, and of pulse rate and ECG, were found with the Nellcor N-595 device using the finger clip, whereas detection of both parameters using the Nellcor N-395 earlobe sensor showed the lowest agreement with the ECG-derived heart rate and SaO_2. These findings suggest that the location of the V-Sign sensor at the ear lobe may not be the optimal place for transcutaneous detection of oxygen saturation and pulse rate in patients early after cardiac surgery.

In conclusion, the SenTec digital V-Sign device in its present state of development has serious limitations. It will be particularly important to improve the stability of the calibration procedure for $PtcCO_2$ and the reliability of SpO_2 and pulse rate detection. Varying interpretations of previously published results may be explained by different pretensions to accuracy.

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