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, Therwil, 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 51–86 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. 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 +0.05 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 PtcCO₂ was observed. Mean bias of SpO₂ 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 PtcCO₂ as well as to improve detection of SpO₂ and pulse rate.

KEY WORDS. combined transcutaneous PCO₂ and SpO₂, 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 sensor
N395-SpO₂ 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-SpO₂ partial oxygen saturation measured by Nellcor N-595, using a finger clip
PaO₂ arterial oxygen tension
PaCO₂ arterial carbon dioxide tension

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Continuous non-invasive monitoring of respiratory parameters is desirable under a variety of circumstances. The use of oxygen saturation as measured by pulse oximetry (SpO2) and capnometric assessment of end-tidal carbon dioxide partial pressure (PETO2) 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, PETO2 is not always accurate [1–4]. In spontaneously breathing patients, correct assessment of PETO2 is difficult [5]. Acute changes in ventilation are first reflected by changes in partial pressure of CO2 (pCO2), whereas the change in oxygenation detected by SpO2 is delayed. In newborns and infants, transcutaneous partial carbon dioxide tension, pulse oximetry oxygen saturation, arterial oxygen saturation, and the TOSCA devise, for combined assessment of transcutaneous partial carbon dioxide tension, pulse oximetry oxygen saturation, arterial carbon dioxide tension (PaCO2), and arterial oxygen saturation (SaO2), and pulse rate derived from the electrocardiography under various clinical conditions in patients early after cardiac surgery, (ii) to assess the agreement of SpO2 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 V5) (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 continuously and noninvasively. It combines the elements of a Stow-Severinghaus-type PCO2 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 PtcCO2 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 (PaCO2), arterial oxygen saturation (SaO2), and pulse rate derived from the electrocardiography under various clinical conditions in patients early after cardiac surgery, (ii) to assess the agreement of SpO2 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.