Cardiac Arrhythmias Decrease Accuracy and Reliability of Third and Fourth Generation Pulse Oximeters.

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Introduction

Cardiac arrhythmias modify the arterial pulse waveform and thus affect verifiably the correct detection of the pulse rate (PR) of pulse oximeters (1). This study was designed to quantify spurious PR readings and to additionally determine whether or not cardiac arrhythmia involves errors in the saturation estimates (SpO2) of third and fourth generation pulse oximeters.

Method

After institutional approval and informed consent, 51 ICU patients (ASA II-IV, mean age 69 yrs) suffering from cardiac arrhythmia (atrial fibrillation, ventricular extrasystoles etc.) were simultaneously connected to a Nellcor N-595, a Philips CMS, and a Masimo SET pulse oximeter utilizing randomly placed proprietary finger probes. Alarm limits of the PR were set at 60 and 120 bpm, respectively, those of the SpO2 to ± 3% (maximum lower alarm limit ≤ 95%) of the fractional hemoglobin saturation (SaO2) subsequent to an initial in vitro blood sample analysis (2*Radiometer OSM3). Patients with low cardiac output were precluded from this study as were patients with inadequate signal strength (perfusion index of Philips CMS < 0.5). SpO2, pulse rate (PR) and heart rate (HR) were recorded continuously and alarm events were classified immediately by a clinically experienced anesthesiologist into technical/physiological and false/correct to calculate sensitivity [TP/(TP + FN)] and specificity [TN/(TN + FP)] (TP = true positive, FP = false positive, TN = true negative, FN = false negative).

Results

The comparison of SaO2 with SpO2 yielded surprisingly low correlation coefficients (CMS: 0.73, N-595: 0.77, Masimo: 0.69), in addition, correlating the pulse oximeters to each other during the entire measuring period returned even lower correlation coefficients for SpO2 (CMS vs. N-595: 0.65, CMS vs. Masimo: 0.51, N-595 vs. Masimo: 0.59). Out of a total of 826 alarm events, false positive (FP) alarms caused by erroneous PR readings were least frequent with N-595 (24; 2.8%), followed by Masimo SET (86; 10.4%), and CMS (141; 17.1%). In contrast to FP alarms FN alarms regarding the pulse rate were rare with all devices: 8 (1.0%) with N-595, 10 (1.2%) with Masimo SET, and 11 (1.3%) with CMS. As a consequence sensitivity appeared consistently high (N-595 97.4%, Masimo SET 94.7%, CMS 97.4%), whereas specificity was lowest with CMS (64.0%) when compared to Masimo SET (86.4%) and N-595 (95.3%). During a total measuring time of 29 hrs, the time in which data were unavailable for technical reasons (INOP), was short for each device: 0.23% with CMS, 0.33% with Masimo, and 0.39% with N-595.

Conclusion

Since SaO2 analysis by a multi-wavelength oximeter was not repeated during the measurements under conditions of hemodynamic stability, SpO2 values exceeding the alarm limits in 20 (39%) patients were not categorized as false positive. However, inadequate agreement with SaO2 and the large variation of SpO2 within the alarm limits as proven by the low correlation between the pulse oximeters evidently reflect a decreased accuracy of SpO2 indications. Largely erroneous PR readings in 29 (57%) patients further reduce the clinical utility of pulse oximeters during cardiac arrhythmias (2) with N-595 performing slightly superior to CMS and Masimo SET.

References: 1. Anesthesiology 2001; 95:A550. 2. Intensive Care Med. 2001; 27:A597.