Rapid Changes in Heart Rate and Oxygen Saturation Decrease the Clinical Performance of Motion-Resistant Pulse Oximeters.

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Introduction

Recent advances in pulse oximetry were focused on signal processing technologies to reliably reject motion artifacts thereby diminishing false positive alarm rates. Since proprietary cardiac-based and saturation-based filtering techniques utilized to appropriately determine pulsatile absorbance may influence the clinical performance, the aim of this clinical study was to evaluate the responsiveness of fourth-generation pulse oximeters to rapid variations of heart rate (HR) and oxygen saturation (SpO2).

Method

After institutional approval and informed consent 82 patients (ASA physical status I-III, mean age 50.4 +/- 17.2 y) receiving electro-convulsive therapy under general anesthesia were included into the study and SpO2, pulse rate (PR) and alarm events were monitored synchronously by means of three pulse oximeters (Philips CMS, Nellcor N-395 and Masimo SET). Finger probes were placed in arbitrary sequence at finger II-IV and, additionally, the ECG's heart rate was recorded as a reference. Alarm events were classified immediately by an experienced anesthesiologist into technical vs. physiological and false vs. correct with the alarm limits (SpO2<90 %, HR<50 bpm and >120 bpm) adjusted to the patient's clinical state prior to treatment. Monitoring data and classified alarm events were stored on a PC and sensitivity and specificity were then calculated off-line and graphically arranged as Receiver Operating Characteristic (ROC) curves. Specificity=TN/(TN+FP) Sensitivity=TP/(TP+FN) TN=true negative alarm, FP=false positive alarm, TP=true positive alarm, FN=false negative alarm

Results

425 alarm events occurred in 60% of all patients (49 out of 82) providing for a total of 605 alarms: 141 (23.3 %) were associated with CMS, 293 (48.4%) with N-395 and 171 (28.3 %) with Masimo. Sensitivity was consistently high with all three devices (CMS: 98 %, N-395: 99 %, Masimo 97 %), whereas statistically significant differences were obtained regarding specificity (CMS: 99 %, N-395: 57 %, Masimo 91 %) (Fig. 1) Synopsizing sensitivity and specificity, ROC curves manifest the Philips CMS slightly superior to Masimo SET and Nellcor N-395. This is confirmed as nearly all positive alarms of the Philips CMS can be categorized as true positive. due to the vast majority of all false positive alarms manifested by the N-395. In 49 patients therapeutic measures were accompanied by the rapid onset of a significant tachycardia (>90 bpm), however, the increase in PR was considerably postponed to the corresponding variations in HR. The average lag time between the PR calculated by the three pulse oximeters and the HR as indicated by the ECG resulted in 20.1 s delay with CMS, 14.2 s with N-395, and 8.2 s with Masimo (Fig. 2)

As INOP times are constantly associated with either tachycardia or a sudden drop in saturation, low INOP ratios (INOP time vs. observation period) demand careful interpretation. Moreover, mild to moderate desaturation occurred in 39 patients with Masimo providing for the majority of

the lowest SpO2 readings (CMS=79+/-10 %, N-395=77+/-12 %, Masimo=72+/-14 %), but the differences in saturation did not prove statistically significant after normalizing the decrease in saturation over the mean variation of SpO2. INOP times accounted for 1.2 % of the observation period with CMS, 2.5 % with Masimo, and 3.1 % with N-395.

Conclusion

With respect to sensitivity, specificity, and INOP time CMS seemed to perform superior, however regarding delay time (PR to HR) Masimo showed the fastest response to rapidly changing parameters. Although the overall performance of the three devices is clinically acceptable, it has to be taken into account that the local detection of SpO2 and PR adds an individually varying circulation lag time to the aforementioned delay time resulting in an additional delay in the appropriate SpO2 indication.

References 1. Barker SJ et al., STA Proceedings 2001:2 2. Jopling MW et al., Anesth Analg 2002;94:S62-S68 3. Lutter N et al., Anesth Analg 2002;94:S69-S75 4. Robertson FA et el, ASA 2002 :A-555