

Pulse oximeters' reliability in detecting hypoxemia and bradycardia: Comparison between a conventional and two new generation oximeters

Bettina Bohnhorst, MD; Corinna S. Peter, MD; Christian F. Poets, MD

Objective: Pulse oximeters are increasingly used for patient monitoring; however, they are traditionally very prone to motion artifact. Newly developed instruments have lower false alarm rates. We wanted to know whether this is achieved at the expense of an increased proportion of false negative alarms such as missed or delayed identification of hypoxemia and/or bradycardia.

Design: Observational study.

Setting: Neonatal intensive care unit.

Patients: A total of 17 unsedated preterm infants (median gestational age at birth, 25 wks; range, 24–30 wks).

Intervention: Long-term recordings of transcutaneous partial pressure of oxygen (P_{TcO_2}), heart rate, pulse oximeter saturation (SpO_2), and pulse rate from a conventional oximeter and two new generation oximeters.

Measurements: Recordings were analyzed for episodes with $P_{TcO_2} < 40$ torr or with heart rate < 80 beats/min for > 5 secs. Hypoxemia was considered identified if SpO_2 had fallen to $< 85\%$ within 2 mins of P_{TcO_2} reaching 40 torr, and bradycardia was considered identified if pulse rate had fallen to < 80 beats/min within 2 mins of the heart rate reaching this threshold.

Main Results: A total of 202 falls in P_{TcO_2} to < 40 torr occurred;

174 (86%) were identified by all three oximeters. Of the remaining episodes, manual analysis of red and infrared absorption signals confirmed that SpO_2 had indeed been $< 85\%$ for ≥ 10 secs in 11 episodes; therefore, these episodes should have been identified by all three oximeters. None of these had been missed by the conventional oximeter, but 10 (5.4% of the total) were missed by one of the new generation instruments (Nellcor), and one (0.5%) was missed by the other (Masimo). Of 54 bradycardias, only 14 were identified by all three oximeters; 17 (32%) were missed by the conventional, 37 (69%) by the Nellcor, and 4 (7%) by the Masimo instrument.

Conclusion: One of the two new generation instruments investigated in this study missed 5.4% of hypoxemic episodes and 69% of bradycardias. It thus appears that this instrument's reduced false alarm rate is achieved at the expense of an unreliable and/or delayed identification of hypoxemia and bradycardia. The other instrument identified both conditions equally as or more reliably than a conventional pulse oximeter. (Crit Care Med 2000; 28: 1565–1568)

Key Words: arterial oxygen saturation; neonatal intensive care; preterm infants; pulse oximetry; sudden infant death syndrome

Pulse oximeters are increasingly used for patient monitoring. The instruments are easy to use, do not require calibration or heating of the skin, and provide almost immediate information regarding changes in arterial oxygenation. Their major disadvantage, however, is their high rate of false alarms, most of which are caused by motion artifact. This not only bears the risk of desensitizing caregivers to true alarms (1, 2), but makes them also quite unsuitable for use as home monitors in patients at increased risk of sudden infant death (3).

Recently developed oximeters appear to have significantly fewer false alarms. One such instrument (Masimo Signal Extraction Technology [SET], Masimo, Irvine, CA) reduces false alarms by mathematically manipulating the pulse oximeter's red and infrared light absorbance to identify and subtract the noise components associated with these signals (4). Compared with a conventional pulse oximeter, it had 93% fewer alarms in one study (5). Another instrument (Nellcor OXISMART, Mallinckrodt Nellcor Puritan Bennett, Pleasanton, CA) relies predominantly on an improved identification of periods where the pulse waveform signal deviates from a predefined template and suppresses any audible alarm for up to 1 min during such periods (6). It was recently shown, however, to result in measurements that are within 7% of control for only 47% to 87% of time during imposed motion (7). Although the other in-

strument (Masimo SET) had performed significantly better in that study (7), we were concerned that such imposed motion may be quite different from that seen in the clinical setting, particularly in infants. We therefore wanted to know whether the reduced false alarm rates of these instruments might result in an increased proportion of missed true alarms such as an impaired detection of hypoxemia or bradycardia. We thus performed long-term recordings of SpO_2 from three pulse oximeters in a group of infants with recurrent hypoxemic episodes and compared these with recordings of a variable that is not affected by motion artifacts, transcutaneous partial pressure of oxygen (P_{TcO_2}) measurements. We wanted to know how many hypoxemic episodes and bradycardias, defined as a fall in P_{TcO_2} to < 40 torr and in heart rate to < 80 beats/min, were missed by the pulse oximeters.

From the Department of Neonatology and Pediatric Pulmonology, Medical School, Hannover, Germany.

Address requests for reprints to: Christian F. Poets, MD, Kinderklinik, Medizinische Hochschule Hannover, 30623 Hannover, Germany. E-mail: Poets.Christian@MH-Hannover.de

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PATIENTS AND METHODS

Recordings were performed in 17 spontaneously breathing unsedated preterm infants with a median gestational age at birth of 25 wks (range, 24–30 wks), birthweight 673 g (range, 520–1575 g), and age at time of study 35 days (range, 8–77 days). All had recurrent apnea of prematurity and were hemodynamically stable, and none had congenital heart disease. All infants had disposable SpO_2 sensors attached to either foot and the left hand, and the signals from these sensors were measured using three different instruments, a conventional pulse oximeter (Nellcor N-200) in 6–7 sec averaging mode, an oximeter with OXISMART technology (Nellcor N-3000) with its variable averaging time (depending on signal quality), and an instrument with Signal Extraction Technology (Masimo SET) in an 8-sec averaging mode. The neonatal sensors used were shielded against each other and against ambient light by dark disposable foam wraps and were resited in 4-hr intervals. Postductal $P_{Tc}O_2$ was measured using a standard $P_{Tc}O_2$ monitor (Kontron 7640, Kontron Instruments, Watford, UK) with the sensor heated to 44°C (111.2°F). The sensor was not placed on bony surfaces and was recalibrated in 4-hr intervals. Under these conditions, there is usually excellent agreement between arterial and transcutaneous PO_2 in hemodynamically stable preterm infants (8, 9). Heart rate was recorded from a standard electrocardiographic monitor (Kontron 7271, Kontron). The SpO_2 and pulse rate readings from the oximeters were recorded together with the data from the $P_{Tc}O_2$ and electrocardiographic monitor using purpose-written software. The raw red and infrared adsorption signal from the Masimo instrument was also recorded. Infants received their routine care throughout the recordings, and treatment of apneas was

not influenced by the study. Alarms on the two new generation oximeters were muted to reduce overall alarm rates. Institutional Review Board approval had been obtained including a written informed consent waiver.

Recordings were analyzed for all episodes during which $P_{Tc}O_2$ fell to <40 torr, the threshold considered to be indicative of clinically relevant hypoxemia (10). Periods where one or several sensors were not attached to the skin, including the first 10 mins after resiting of the $P_{Tc}O_2$ sensor (when the skin was still being warmed up by the sensor) were not screened for hypoxemic episodes. Periods with disturbed pulse oximeter signals attributable to movement artifact or caretakers' interventions, however, were not excluded from analysis. Episodes where a fall in $P_{Tc}O_2$ to <40 torr had occurred extremely slowly (<20% change within 2 mins) were excluded to reject episodes where the fall in $P_{Tc}O_2$ was likely to reflect poor skin perfusion rather than arterial hypoxemia (3). Episodes were then analyzed as to whether they were associated with a fall in SpO_2 to <85% occurring within 2 mins of the fall in $P_{Tc}O_2$ to <40 torr. PO_2 of 40 torr corresponds to an oxygen saturation of ~78% to 84%, depending on the proportion of fetal hemoglobin (11). If SpO_2 readings from an oximeter had stayed $\geq 85\%$ throughout the fall in $P_{Tc}O_2$ to <40 torr, SpO_2 was determined manually from the raw red and infrared adsorption data following standard procedures (12), and the episode was excluded from analysis if SpO_2 had not been <85% for ≥ 10 secs (the latter interval was chosen to account for averaging times). The latter analyses were done without knowledge of which oximeter had failed to alarm and was introduced to ensure that the fall in $P_{Tc}O_2$ had not occurred as a result of poor skin perfusion.

Recordings were also analyzed for the bradycardias that were not accompanied by a fall in $P_{Tc}O_2$ to <40 torr that would have gone undetected if only oxygenation had been monitored. A bradycardia was defined as a fall in heart rate to <80 beats/min for >5 secs (13). These bradycardias were checked as to whether they were accompanied by a fall in pulse rate to <80 beats/min of any duration occurring within 2 mins of the fall in heart rate.

RESULTS

Median duration of recording with analyzable signal was 13 hrs (range, 5–36 hrs). During this time, 202 falls in $P_{Tc}O_2$ to <40 torr occurred, with a range of 1 to 34 episodes per infant (median, 12 episodes per infant). Of these, 174 (86%) were identified by all three oximeters (Fig. 1). In 15 of these episodes, however, the N-200 alarmed because it had zeroed out from signal loss; this happened four times with the OXISMART and only once with Masimo SET.

Of the remaining 28 episodes where an oximeter had not alarmed, manual analysis of red-to-infrared ratios showed that SpO_2 had been <85% for <10 secs or had not been <85% at all in 16 episodes. During one additional episode, the pulse waveform signal was so grossly disturbed by artifact that it was impossible to determine SpO_2 , leaving 11 out of 185 true hypoxemic episodes that were missed by at least one oximeter. All 11 episodes were identified by the conventional oximeter (N-200), whereas 10 (5.4%; in 5 infants) were missed by Nellcor OXISMART and 1 (0.5%) by the Masimo SET. The duration of time during which SpO_2 had been <85% according to manual analysis ranged from 10 to 32 secs (median, 15.2 secs) for the Nellcor and was 12 secs for the Masimo instrument.

The mean interval between $P_{Tc}O_2$ falling to <40 torr and SpO_2 falling to <85% was -0.7 secs (SD, 0.5 secs) for the conventional and -0.4 secs (SD, 0.4 secs) for both new generation instruments. On average, all three oximeters alarmed some 0.4–0.7 secs before the $P_{Tc}O_2$ monitor reached the corresponding alarm threshold.

There were 54 bradycardias in 11 infants that were not accompanied by hypoxemia. Only 14 of these (26%) were identified by all 3 oximeters. Of the 40 bradycardias that were not identified, 37 (69%) were missed by the Nellcor OXISMART, 4 (7%) by Masimo SET (all

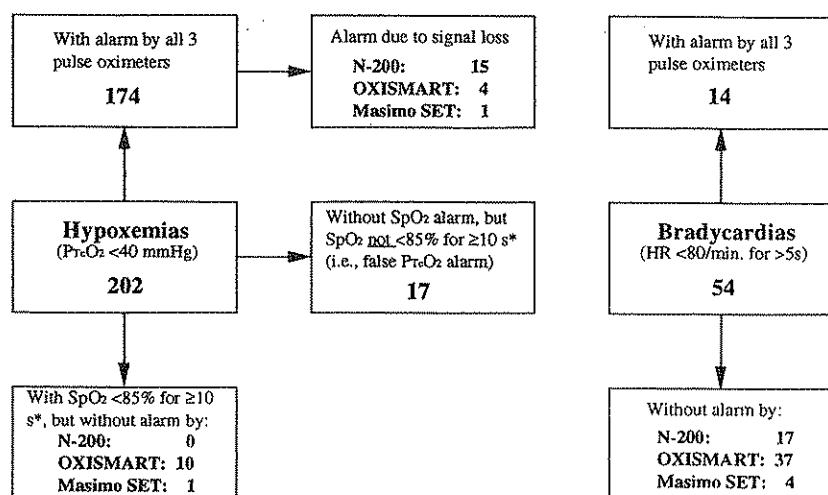


Figure 1. Distribution of hypoxemia and bradycardia alarms identified with the instruments investigated in this study. * SpO_2 determined by manual analysis of red and infrared absorption signals.

had also been missed by the OXISMART), and 17 (32%) by N-200 (14 of these had also been missed by the OXISMART).

DISCUSSION

Prolonged apnea or bradycardia, the conditions traditionally identified by monitors both at home and in the nursery, occur in only 10% and 28%, respectively, of severe hypoxemic/cyanotic episodes (3). Also, cardiorespiratory monitors only alarmed when infants were already gasping and severely hypoxemic in 7 of 9 sudden infant deaths that were recorded using documented monitoring (14). Monitoring of oxygenation would seem the logical consequence, yet it appeared impractical because P_{TcO_2} monitors are difficult to use and conventional pulse oximeters have an unacceptably high false alarm rate (2, 4). The latter problem appears to have been overcome with the two new oximeters investigated in this study. We now wanted to know whether this reduction in false alarm rates had been achieved at the expense of an impaired or delayed detection of hypoxemia.

Using a combination of continuous P_{TcO_2} measurements and manual analysis of red-to-infrared ratios as a criterion, we identified marked differences in the reliability with which the three pulse oximeters investigated in this study identified hypoxemia. The Nellcor N-200 alarmed during all hypoxemic episodes (although during 15 of these, it only alarmed because of signal loss), and one of the two new generation instruments (Masimo SET) missed only one out of 185 episodes. In contrast, the other new generation instrument (Nellcor OXISMART) failed to alarm in 5.4% of episodes where there was definite hypoxemia, despite the latter lasting for up to 32 secs. The pulse oximeters' ability to identify bradycardia differed even more widely, with more than two thirds of episodes missed by the new Nellcor and one third missed by the conventional Nellcor instrument. The Masimo SET again performed significantly better, missing only 4 of 54 bradycardias. Thus, the reduced false alarm rate of one of the 2 new generation instruments investigated in this study appears to have been achieved at the expense of a reduced ability to identify true alarms, hypoxemia and particularly bradycardia.

Is the combination of P_{TcO_2} measurements and manual analysis of red-to-

infrared ratios an appropriate criterion for the identification of hypoxemia? Clearly, measurements of arterial P_{O_2} from arterial catheters would have been preferable, but were considered both unethical and impractical with the unpredictable and short-lived hypoxemic episodes occurring in these infants. We thus chose the above combination of analytical methods for both methodologic and practical reasons. P_{TcO_2} measurements are not affected by body movements, the major cause of erroneous Sp_{O_2} readings in infants, but are more dependent than Sp_{O_2} measurements on skin blood flow (3, 9). We reasoned, however, that there was nothing to suggest a change in skin blood flow as the cause of a fall in P_{TcO_2} if the Sp_{O_2} measured by all three oximeters had fallen to below the alarm threshold. However, we excluded poor skin perfusion as a cause of falsely low P_{TcO_2} readings by performing a manual analysis of red-to-infrared ratios (12) in those episodes in which an oximeter had failed to alarm and found that Sp_{O_2} had indeed stayed at $\geq 85\%$ in a considerable proportion of episodes.

We did not analyze caregivers' responses to alarms. This prohibited an assessment of the clinical relevance of the hypoxemic episodes recorded, but was considered necessary to avoid observer bias. Nevertheless, a bias might have resulted from the fact that alarms on the two new generation oximeters were muted. This, however, cannot explain the differences observed between these two instruments.

P_{TcO_2} monitors have ~a 20 sec response time to a sudden change in Pa_{O_2} (3, 9). It is therefore possible that some brief hypoxemic episodes that were too short to result in a fall in P_{TcO_2} to < 40 torr were missed. Our aim, however, was to concentrate only on relatively prolonged and severe episodes, because it is only during these that it is clinically relevant for a pulse oximeter to sound an alarm. Given this long response time, plus the 2-min time frame allowed for any Sp_{O_2} alarm to occur, the failure of the OXISMART to identify 5.4% of hypoxemic episodes cannot be sufficiently explained by the variable averaging mode used in its software. It is more likely related to its method of "freezing in" the last apparently reliable value for up to 1 min during artifact conditions (Fig. 2); if the memory is then updated by one falsely high value that may also remain displayed for another minute, a considerable delay in

This first comparative analysis of three pulse oximeters' ability to detect sudden hypoxemia and bradycardia in patients with frequent body movements has shown that the improvement in false alarm rate achieved with some new developments may be associated with a reduced or delayed detection of true alarms.

alarming to hypoxemia may result. Because the OXISMART was not used as the sole monitor in this study, it remains unclear whether this instrument's failure to alarm to hypoxemia within our 2-min time frame is clinically relevant and whether it could result in a failure to alarm early enough for effective intervention, as was observed with some cardiorespiratory monitors during sudden infant deaths (14). For obvious ethical reasons, this question cannot be addressed prospectively.

The N-200 alarmed during all hypoxemic episodes. This encouraging result, however, was somewhat diminished by the fact that the instrument zeroed out during 15 (8%) of these episodes. This feature does not help the clinician to decide whether or not the patient is hypoxemic, but at least it alerts him or her to check on the patient's condition; this is still preferable to a nonalarm situation. Combined with the high false alarm rate of this instrument, however, the frequent zero-out occurrences also bear the risk of desensitizing caregivers, thereby delaying responses to true alarms (1, 2).

The oximeters' ability to detect decreases in pulse rate was worse than their ability to detect hypoxemia. This may not be surprising given that the instruments are mainly designed to identify hypoxemia. In the intensive care unit setting, it may not even be relevant because brady-

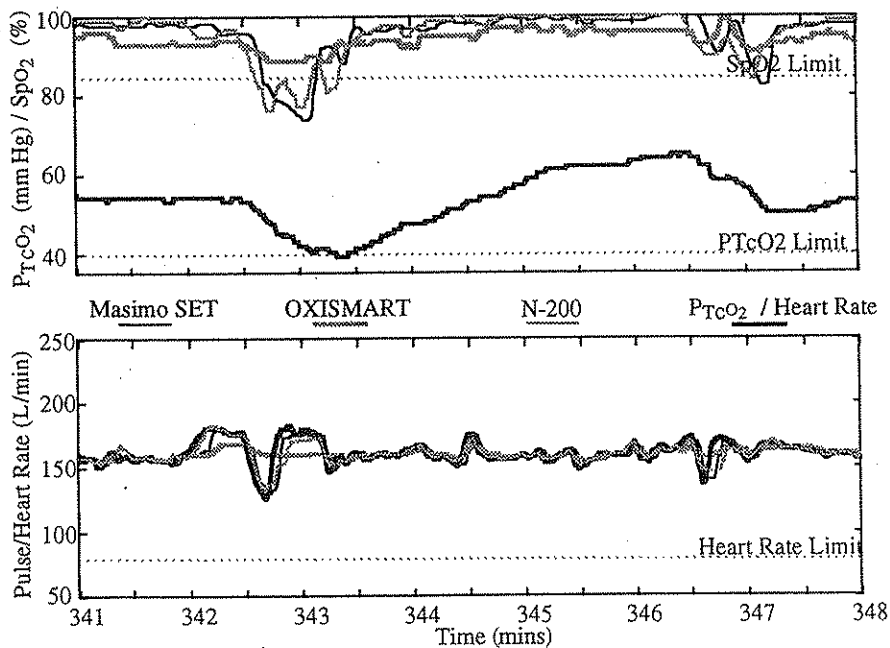


Figure 2. Example of a hypoxemic episode that was missed by Nellcor OXISMART. There is a fall in P_{TcO_2} to 39 torr, associated with a fall in SpO_2 to 72% as determined by manual red-to-infrared analysis with SpO_2 being $<85\%$ for 16 secs. The Nellcor N-200 and Masimo SET fall to $<85\%$ 42 secs and 36 secs before P_{TcO_2} drops to <40 torr. In contrast, the Nellcor OXISMART continues to display SpO_2 readings above the alarm threshold throughout the episode; both its SpO_2 and pulse rate readings appear to have been temporarily frozen.

cardia detection usually occurs there via electrocardiographic monitoring. For use as home monitors, however, reliable detection of bradycardias occurring without hypoxemia appears important. In this regard, it is alarming that the OXISMART missed two thirds of these events. Although numbers are small, it becomes clear that the pulse rate algorithm built into this instrument requires some improvement before this monitor can be recommended for use at home. The considerably better results of the Masimo SET may be related to the fact that its pulse rate algorithm operates completely independent from its SpO_2 algorithm (J. Kiani, oral communication, May 1998).

In conclusion, this first comparative analysis of three pulse oximeters' ability to detect sudden hypoxemia and bradycardia in patients with frequent body

movements has shown that the improvement in false alarm rate achieved with some new developments may be associated with a reduced or delayed detection of true alarms. The Nellcor OXISMART missed 5% of hypoxemic episodes and two thirds of bradycardias. In contrast, the Masimo SET oximeter investigated in this study detected hypoxemia and bradycardia equally or even more reliably than a conventional pulse oximeter.

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