A Prospective Comparison of 3 New-Generation Pulse Oximetry Devices During Ambulation After Open Heart Surgery

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OBJECTIVE: To assess the clinical performance of 3 new-generation pulse-oximetry signal-processing software systems (Philips FAST, Masimo SET, and Nellcor N-3000) during ambulation after open-heart surgery. DESIGN: Prospective, convenience sample. SETTING: Cardiac surgical progressive care unit in a 629-bed, not-for-profit, tertiary-care teaching hospital. PATIENTS: Status post-cardiac-surgery patients (n = 36) during their first postoperative ambulation. INTERVENTIONS: None. PROTOCOL: Randomization was used for digit and hand selection, and all 3 devices were used continuously during ambulation. Data on dropouts, false alarms, and correlation with heart rate were recorded. We continuously measured arterial oxygen saturation via pulse oximetry during ambulation with all 3 devices. RESULTS: Pairwise comparisons indicated significant differences among the 3 devices for data dropout and false alarm. In repeated-measures analysis, the Nellcor N-3000 had the greatest likelihood of data dropout (odds ratio of 31.9 to Masimo and 5.6 to Philips, at the 95% confidence interval). However, the converse was true for false alarms; the Masimo had the most false alarms, with an odds ratio of 17.9 to Nellcor and 2.3 to Philips, at the 95% confidence interval. There were also significantly more dropouts with all 3 devices when readings were taken on a hand on an arm from which a radial graft had been taken (p = 0.004). For heart-rate correlation, the mean absolute difference among the 3 devices was similar: Philips = 4.3 beats/min, Masimo = 5.1 beats/min, and Nellcor = 3.0 beats/min. CONCLUSIONS: There are significant differences among the 3 devices with regard to dropout and false alarms. High numbers of dropouts are problematic because no pulse-oximetry patient information is available during dropout. However, false alarms are even more problematic, because they desensitize clinicians to alarms and call into question the accuracy of displayed data. While our data highlight the statistical differences between the studied oximeters, the clinical implications of these differences warrant further study. *Key words: oximetry, monitoring, sensitivity and specificity, postoperative complications.* [Respir Care 2006;51(1):29–35. © 2006 Daedalus Enterprises]

Introduction

Measurement of oxygen saturation in conventional pulse oximetry is accomplished through the application of the Lambert-Beer law. The Lambert-Beer law describes the relationship between a colored substance, the length of the path on which light can pass through it, and the corresponding light absorption by that substance.[1,2] In the clinical measurement of arterial oxygen saturation by pulse oximetry (S_{pO_2}), 2 light-emitting diodes (LEDs) emit light

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of different wavelengths, red and infrared, which are passed through the tissue of the finger, toe, earlobe, or nose. The more oxygenated the blood, the more red light and the less infrared light passes through. Conversely, when blood oxygenation is low, less red light and more infrared light passes through. S_{pO_2} is calculated by determining the ratio of red to infrared light change over time, using a light-sensitive photodiode.

One of the most important disadvantages of conventional pulse oximetry is its vulnerability to motion artifact. Motion artifact occurs either when the S_{pO_2} monitor incorrectly interprets patient movement as a pulse signal, or when the patient's motion renders the S_{pO_2} monitor unable to accurately identify the patient's true pulse signal. Manufacturers of pulse oximetry technology have sought to improve the software algorithms used to calculate S_{pO_2} so that motion artifact can be eliminated from the pulse oximetry signal. These algorithm changes have created a new group of pulse oximeters that are generally referred to as "new-generation" or "motion-tolerant" pulse oximeters and have been specifically designed for improved clinical performance. While there are some data in the literature that can be used by clinicians to assess the clinical performance of these new-generation pulse oximeters, to date, peer-reviewed scientific publications evaluating the new, motion-tolerant pulse oximeters in real clinical settings are few and are basically limited to only 3 of the current devices on the market:[3–14] FAST (Fourier Artifact-Suppression Technology, Philips Medical Systems, Andover, Massachusetts), SET V2 (Signal-Extraction Technology, Masimo, Irvine, California), and Oxismart N-3000 (Nellcor, Pleasanton, California). We acknowledge that manufacturers are constantly revising their products and releasing new software; however, not all clinicians have access to the newest software revisions, which makes relevant this comparison of these 3 pulse-oximetry systems, which continue in clinical use.

Methods

Purpose and Research Question

The purpose of this study was to compare the clinical performance of 3 new-generation pulse oximeters with cardiac surgery patients during their first postoperative ambulation. This is a group of patients with whom pulse oximetry is important because of potential physiologic compromise that can occur during the first postoperative ambulation. This is also a situation where motion artifact is a factor. The 3 S_{pO_2} systems we studied were (1) the Philips FAST system, used with the M3 patient monitor and the M1191A adult finger sleeve sensor (Philips Medical Systems, Andover, Massachusetts), (2) the Masimo SET V2, used with the LNOP DCI adult clip sensor (Masimo, Irvine, California), and (3) the Nellcor N-3000, used with the DS100A adult clip sensor (Tyco International, Pleasanton, California). The study was designed to answer the question: Is there a difference in the amount of data dropout, the number of false alarms, and the heart-rate (HR) correlation between the 3 devices when used with cardiac surgery patients during their first postoperative ambulation?

Subjects

The study was conducted at Saint Luke's Hospital, Kansas City, Missouri, a tertiary-care teaching hospital. After institutional-review-board approval of the study, subjects were recruited from the 33-bed cardiovascular surgery progressive-care unit. The subjects were status post-open-heart-surgery patients during their first postoperative ambulation. The final sample consisted of 36 adult patients (39–80 years of age) admitted to the progressive-care unit after cardiac surgery (coronary artery bypass graft, valve replacement, and septal defect surgeries). Study participants were recruited from all eligible patients, using a convenience sampling strategy during the enrollment period. The study procedure was explained to all subjects, and informed consent was obtained prior to data collection. Subjects were approached by the principal investigator, who described the purpose and procedure for data collection in terminology understandable to the patients. It was emphasized that participation was voluntary and that, rather than monitor their oxygen status during ambulation with one device, we would use 3 devices and take periodic readings from all 3 devices for comparison. Table 1 shows the patient demographics and other characteristics.

Protocol

Although the institutional review board waived the requirement for signed informed consent, the principal investigator asked the subjects for verbal consent. The principal investigator or a research assistant who was trained in the study protocol completed the data collection. The subjects were monitored continuously and simultaneously by all 3 pulse oximeters, as well as by a centralized cardiac telemetry monitor (Patient Net, version 1.03, GE Medical Systems Information Technologies, Milwaukee, Wisconsin). The index finger, middle finger, and ring finger of both hands were used for pulse-oximetry sensor placement during ambulation, and were labeled as right or left digit 2 (index), 3 (middle), and 4 (ring). No artificial nails or nail polish was allowed. Digit placement of the sensors was randomized for each device, using a random-numbers table to assign each device to a digit for each patient. All 3 pulse oximeters were placed on a mobile cart and accompanied the patient during ambulation. The amount of data dropout and the number of false alarms were recorded

Table 1. Patient Characteristics*

Age (mean ± SD y)	63 ± 12
(median and range y)	65 (39–80)
Male (number and %)	25 (69.4)
Admit diagnoses (number and %)	
Coronary artery disease	23 (63.9)
Other	18 (50.0)
Diabetes (number and %)	14 (38.9)
Peripheral vascular disease (number and %)	2 (5.6)
Surgery (number and %)	
Isolated coronary artery bypass graft	16 (44.4)
Coronary artery bypass graft + other	8 (22.2)
Total Coronary artery bypass graft	24 (66.6)
Coronary artery bypass graft × 1	2 (5.6)
Coronary artery bypass graft × 2	6 (16.7)
Coronary artery bypass graft × 3	8 (22.2)
Coronary artery bypass graft × 4	6 (16.7)
Coronary artery bypass graft × 5	2 (5.6)
Other	12 (33.3)
Cardiovascular intensive care unit stay	
(mean ± SD h)	27.4 ± 10.9
(median and range h)	23 (15–57.5)
Last hemoglobin (mean ± SD g/dL)	10.0 ± 1.3
(median and range g/dL)	9.9 (7.5–12.8)
Last hematocrit (mean ± SD %)	29.1 ± 4.0
(median and range %)	29 (21–36)
Post-operative ventilator time (mean ± SD h)	9.7 ± 4.0
(median and range h)	9.875 (3.75–25.75)
Pre-Ambulation Vital Signs	
Heart rate (mean ± SD beats/min)	81 ± 12
(median and range beats/min)	80 (60–109)
Rhythm (number and %)	
Sinus rhythm	26 (72.2)
Normal sinus rhythm	2 (5.6)
Paced	6 (16.7)
Atrial fibrillation	2 (5.6)
Systolic blood pressure (mean ± SD mm Hg)	111 ± 13
(median and range mm Hg)	110 (80–140)
Diastolic blood pressure (mean ± SD mm Hg)	61 ± 9
(median and range mm Hg)	60 (33–78)
Oxygen support (L/min)	
Median (Range)	2 (0–7)
0 (room air)	9 (25.0%)
1	2 (5.6%)
2	12 (33.3%)
≥ 3	13 (36.1%)
Ambulation Post-operative day	
Median (Range)	2 (0–3)
0	2 (5.6%)
1	2 (33.3%)
2	20 (55.6%)
3	2 (5.6%)
Duration (median and range min)	4 (2–9)
Radial graft in same arm (number and %)	17 (47.2)

*Data collection occurred between September 11, 2002 and January 31, 2003. $n = 36$

manually during the ambulation period. Using a stopwatch, each device's values were recorded on the minute. During each minute interval, if a false alarm or episode of dropout occurred, a notation was made. A nurse accompanied the patient while another nurse collected data. Data collection was synchronized to start with the exact time on the electrocardiogram monitoring system in order to compare heart-rate values.

No attempt was made to quantify patient motion, as has been done in laboratory research on pulse oximetry. However, since the sensors were placed simultaneously on the fingers of each subject, all the sensors were subjected to the same type of motion with each patient. Patients were allowed to ambulate however they were most comfortable, utilizing a grocery cart for support, which is our standard practice.

Data dropout was defined as a loss of signal initiating an alarm: "sensor off" with the Masimo device, "S_{pO_2} non-pulsatile" with the Philips device, and "pulse search" with the Nellcor device. A false alarm was defined as a spurious saturation of $\leq 90\%$ with either (1) an additional lack of correlation between the HR reading from the oximeter and the reading from the electrocardiograph or (2) a value that differed significantly from the other 2 devices when those devices were recording S_{pO_2} values $> 90\%$.

The signal-averaging time was set as similar as possible for these 3 devices: Philips device at 10 s, Masimo device at 10 s, and Nellcor device (on which there is no 10-s option) at 7 s. All 3 devices were set with the S_{pO_2} low alarm limit at 90% and high alarm limit at 100%.

Statistical Analysis

Each data-collection sheet was reviewed for accuracy and completeness by the principal investigator prior to entry into the statistical analysis program, to assure accuracy and completeness of the data. Descriptive statistics were generated for each variable of interest, and all variables were closely examined for any missing data, outliers, and skewness. Medians, means, modes, and standard deviations were computed for all interval data, and frequency counts and percentages were provided for categorical data. Pairwise comparisons of pulse readings among the devices were conducted using scatter plots and Bland-Altman plots and summarized by median and mean absolute difference.

The likelihoods of data dropout and of false alarms were compared using repeated-measures logistic regression, including fixed effects for device, digit, hand, presence of diabetes, radial graft from the arm, and random effects for patient and patient by time. Effect estimates were derived using the %GLIMMIX (General Linear Model for Mixture Distributions) macro in the SAS System for Mixed Models (SAS Institute, Cary, North Carolina).

Table 2. Average Dropouts and False Alarms Per Patient

	Average Dropouts and False Alarms Per Patient (mean ± SE)*		
	Philips FAST	Masimo SET	Nellcor N-3000
Dropouts per patient			
Mean	21.4	5.9	41.9
Median (interquartile range)	0 (0–44)	0 (0–0)	45 (0–79)
False alarms per patient			
Mean	12.4	19.6	2.3
Median (interquartile range)	0 (0–24)	8 (0–37)	0 (0–0)
Dropouts or false alarms per patient			
Mean	29.3	24.3	42.7
Median (interquartile range)	20 (0–50)	20 (0–37)	45 (0–82)

*36 patients

Results are presented as odds ratios with 95% confidence intervals, and p values for likelihood of dropout or false alarm. The p values and confidence intervals were adjusted for a priori pairwise comparisons, using simulation-based adjustments to account for correlations among tests.[15–16]

Results

Table 2 shows the average amount of data dropout and false alarms per patient. The Nellcor has the highest percentage of data dropout per patient and the Masimo has the least, with the Philips performing in between. The device performance is reversed for false alarms; the Masimo has the most false alarms, the Nellcor has the least, and the Philips is in between. In these analyses the Masimo is functional for the greatest percentage (75.7%) of the time per patient, followed by the Philips (71.7%), and the Nellcor (57.3%). From a clinical standpoint this is important because it represents the total amount of time that the device is not able to provide any clinically meaningful data.

Tables 3 and 4 show the logistic regression analysis of data dropout and false alarms for each of the 3 device pairs. The odds ratios show that, again, there are statistically significant differences in performance among the 3 device pairings for both data dropout and false alarms. There is also a statistically significant difference in data dropout (but not false alarms) between patients with and without radial artery grafts. Finally, there is a statistically significant difference in false alarming based on which digit the sensor is placed on.

Table 5 and Figures 1 and 2 examine the 3 devices' performance in HR measurement as compared to the HR measurements of the centralized telemetry monitoring system. Table 5 shows the mean and median differences between the pulse readings from the oximeters and those from the cardiac monitor, as well as the mean absolute difference, which gives you an idea of how different (plus or minus) the pulse and HR values are on average. This could be considered as a measure of clinical accuracy. As you can see from the results, there are no differences in mean device performance with regard to HR accuracy across any of the tested devices.

Table 3. Model-Based Odds Ratios for Data Dropout

	Data Dropout		
	Odds Ratio	95% Confidence Interval	p
Device			<0.0001
Philips vs Masimo	5.7	2.2–14.9	<0.0001
Nellcor vs Philips	5.6	2.7–11.4	<0.0001
Nellcor vs Masimo	31.9	12.0–85.2	<0.0001
Digit			0.382
3 vs 4	1.2	0.6–2.4	
2 vs 3	1.3	0.7–2.7	
2 vs 4	1.6	0.8–3.1	
Hand (right vs left)	5.9	1.4–25.2	0.023
Diabetes	1.1	0.3–4.8	0.875
Radial graft	12.4	2.6–59.4	0.004

Table 4. Model-Based Odds Ratios for False Alarms

	False Alarms		
	Odds Ratio	95% Confidence Interval	p
Device			< 0.0001
Philips vs Masimo	7.9	3.4–18.4	< 0.0001
Nellcor vs Philips	2.3	1.3–3.8	0.0007
Nellcor vs Masimo	17.9	7.7–41.3	< 0.0001
Digit			< 0.0001
4 vs 3	1.7	1.0–2.9	
2 vs 4	2.0	1.2–3.4	
2 vs 3	3.3	2.0–5.7	
Hand (right vs left)	1.4	0.5–4.3	0.531
Diabetes	2.0	0.7–5.9	0.235
Radial graft	1.5	0.5–4.8	0.485

Table 5. Summary of Differences Between Heart-Rate Readings From the Pulse Oximeters and Heart-Rate Readings From the Cardiac Monitor

	Philips FAST	Masimo SET	Nellcor N-3000
Median difference (beats/min)	0	0	1
Mean absolute difference (beats/min)	4.3	5.1	3.0

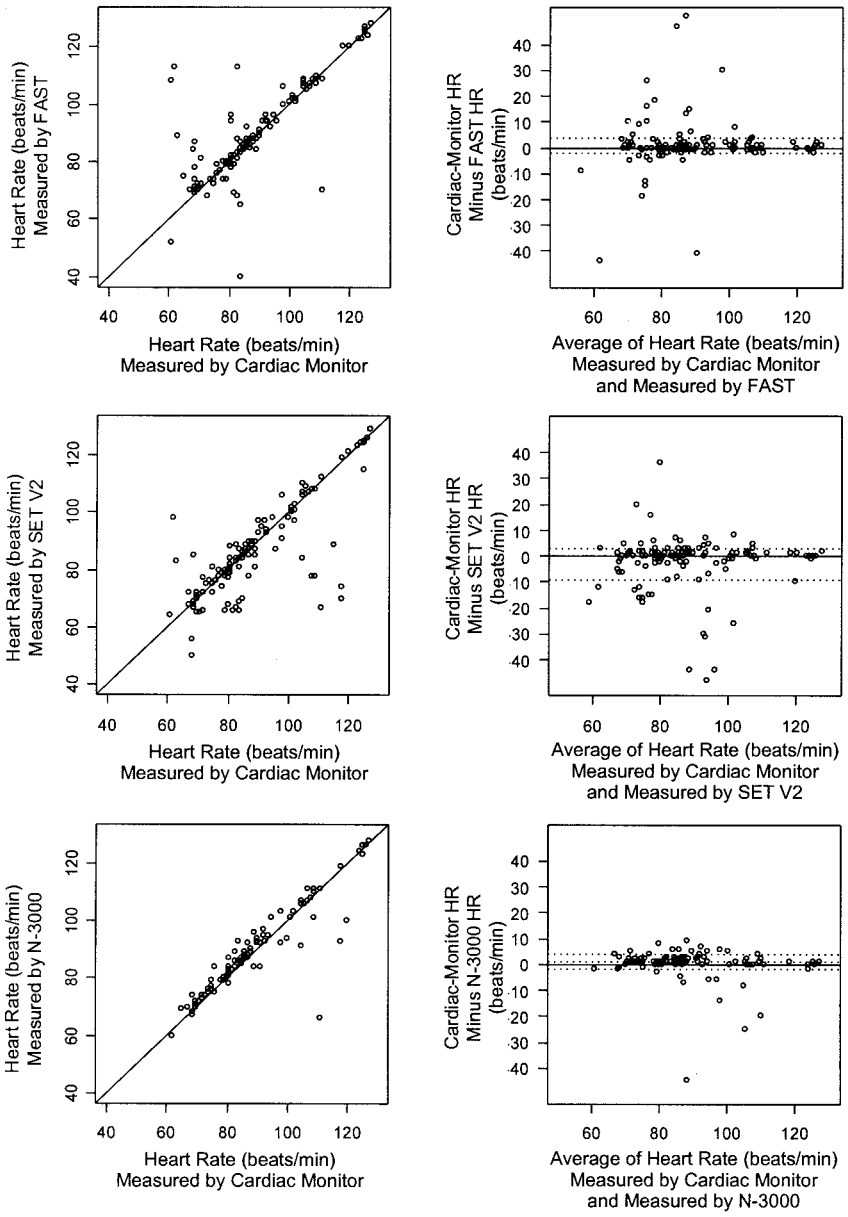

Fig. 1. Scatter plots and Bland-Altman-type plots of heart rate measured by the centralized cardiac monitor versus heart rate measured by the 3 studied pulse oximeters: Philips FAST (Fourier Artifact-Suppression Technology), Masimo SET V2 (Signal-Extraction Technology), and Nellcor Oxismart N-3000. In the Bland-Altman plots (right column) the dashed lines denote the median and middle 80% of the data.

Figure 1 shows the scatter plots and Bland-Altman-type plots. The dotted lines denote the median and middle 80% of the data rather than mean ± 2 standard deviations, since the data are not normally distributed. It can been seen by these scatter plots that all 3 devices have the majority of their data points close to the HR measured by the centralized telemetry monitoring system. The highest concordance was seen with the Nellcor device, with 80% of readings within ± 5 beats/min of HR, no readings more than 10 beats/min greater than HR, and only 4 more than 10 beats/min under HR. Greater variability was observed with the Philips and Masimo devices; in particular, the Masimo device had the strongest tendency to underestimate HR.

Figure 2 shows the percent of pulse readings within a given range from the HR value (again, plus or minus). For example, in Figure 2, 20% of the pulse readings equaled the measured HR exactly (absolute difference = 0 on the X axis) for all 3 devices. However, about 70% of the readings for the Philips and Nellcor devices were within ± 2 beats/min of the HR, compared to 60% of the readings

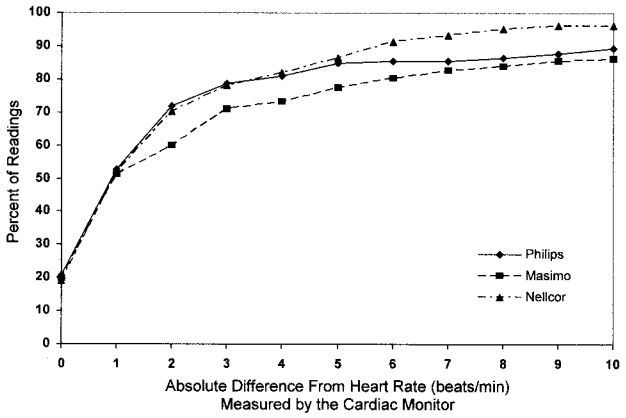

Fig. 2. Pulse readings from the 3 studied pulse oximeters relative to the absolute deviation of heart rate.

Table 6. False Alarms by Digit

	False Alarms		
	Digit 2 (index finger)	Digit 3 (middle finger)	Digit 4 (ring finger)
Overall	15	9	13
Intact radial artery	8	4	4
Radial artery graft	7	5	9

from the Masimo device. In general, it can be seen by reviewing the data plots that all 3 devices were similar in performance with regard to HR measurement.

We also noted a statistically significant difference in false alarms based on which digit was used for sensor placement, and these results are presented in Table 6. Overall, in all patients, digit 3 (middle finger) yielded the least false alarms, followed by digit 4 (ring finger). Digit 2 (index finger), which many clinicians use for sensor placement, had the overall highest false alarm rate. On arms that had intact radial arteries, digits 3 and 4 again showed fewer false alarms than digit 2. Finally, when the sensor was placed on digits on the same arm where a radial artery graft had been taken, digit 3 still had the lowest false alarm rate, again followed by digit 2, then digit 4.

Discussion

Data dropout during S_{pO_2} monitoring is important because no clinical patient information is available during dropout. The more dropout occurs, the less clinicians will see the value of monitoring S_{pO_2}. Our results indicate there was a difference in performance across the 3 devices. The Nellcor device had the most dropout, followed by the Philips device, then the Masimo device. Additionally, when dropout occurs, it generates another alarm tone in an environment already saturated with noise and alarms. The risk is that clinicians may become complacent and ignore alarms.[17]

Also of interest was a statistically significant difference in dropout between patients with and without radial artery grafts. When S_{pO_2} was monitored using the same hand/arm that had also donated a radial artery graft, there was more dropout. This has clinical implications for practice, especially in this patient population. These data suggest that the oximetry sensor should be placed on the hand on the arm that has an intact radial artery.

Data dropout is important, but false alarms are perhaps even more worrisome, as they desensitize staff responses. Our study demonstrated a difference in performance related to false alarming among the 3 devices. The Masimo device had the most false alarms, followed by the Philips device; the Nellcor device had the least. False alarms not only desensitize staff, but they call into question the accuracy of displayed data. Device performance was reversed when looking at false alarms, as compared with dropout. Apparently, obtaining accuracy in one (false alarms or dropout) comes at the expense of the other. The device with the least dropout (Masimo) had the most false alarms, and the device with the least false alarms (Nellcor) had the most dropout. The Philips performed in between the Nellcor and Masimo for both dropout and false alarm. There was no statistically significant difference in dropout based on digit used for monitoring.

We noted a statistically significant difference in false alarms based on which digit was used for sensor placement. This too has clinical importance, since our data support that the middle finger appears to be the preferred site for digital sensor placement to avoid false alarms. Additionally, digit 2, which is probably the most common site used for S_{pO_2} monitoring, appears to yield the most false alarms with a moving patient. Monitoring practices should take this data into consideration when applying S_{pO_2} sensors on patients in the clinical setting.

The combined total amount of time each device was in dropout or false alarm is important clinically because it represents the total amount of time that the device is not able to provide any clinically useful data. The Masimo is functional for the greatest amount of time, followed by the Philips, then the Nellcor. But, again, the Masimo had the most false alarms, calling into question the accuracy of displayed data.

HR correlation was studied by measuring each oximeter's displayed pulse rate and comparing it with the hospital's centralized telemetry monitoring system HR value. Collection of both (oximeter and telemetry) readings was synchronized. This can be considered a measure of clinical accuracy. Our results indicated no differences in mean device performance with regard to HR accuracy. These

devices all performed well, with approximately 70% of all readings from the Philips and Nellcor giving readings within ± 2 beats/min of the HR, and Masimo achieved this level of accuracy with 60% of all its readings. Clinically, this ability to trust oximeter pulse/HR data as accurate is reassuring for both practitioners and patients.

There were some limitations to our study. It was not possible to blind clinicians to the oximeters being evaluated, so we are unsure whether this affected our outcomes. Skin color is a variable that can affect oximeter accuracy and was not measured in our study.[18] Another limitation was the use of 2 different sensor types. The Nellcor and Masimo use adult clip sensors and the Philips uses a finger-sleeve sensor. Although there were no issues with sensors falling off of digits, perhaps using the same sensor type for all 3 devices would be recommended. Lastly, we used popular devices that are in current use throughout the country, making the comparison clinically relevant; however, a comparison of each vendor's newest software may be an opportunity for future research.

Conclusions

This study shows that there are differences across all 3 devices with regard to both dropout and false alarm. High amounts of dropout are problematic, because no clinical patient information is available during dropout. However, false alarm are even more problematic, because they desensitize the clinicians to alarms and call into question the accuracy of displayed data. While these data highlight the statistical differences in the S_{pO_2} devices that were studied, the clinical implications of these differences warrant further study.

Manufacturers have worked to improve pulse oximetry technology, and we now have some quite reliable devices from which to choose. Future industry efforts should continue to focus on providing uninterrupted accurate data with as little false alarming and erroneous-value-display as possible. Other aspects of device performance that need improvement include reliability during hypoperfusion states and during intra-aortic balloon-pump therapy. There is also a need for more pulse oximetry research on clinical outcomes, such as activity progression in specific patient populations and weaning time from mechanical ventilation.

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