EVALUATION OF A NEW PULSE OXIMETER SENSOR

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• BACKGROUND A new forehead noninvasive oxygen saturation sensor may improve signal quality in patients with low cardiac index.
• OBJECTIVES To examine agreement between oxygen saturation values obtained by using digit-based and forehead pulse oximeters with arterial oxygen saturation in patients with low cardiac index.
• METHODS A method-comparison study was used to examine the agreement between 2 different pulse oximeters and arterial oxygen saturation in patients with low cardiac index. Readings were obtained from a finger and a forehead sensor and by analysis of a blood sample. Bias, precision, and root mean square differences were calculated for the digit and forehead sensors. Differences in bias and precision between the 2 noninvasive devices were evaluated with a t test (level of significance P < .05).
• RESULTS Nineteen patients with low cardiac index (calculated as cardiac output in liters per minute divided by body surface area in square meters; mean 1.98, SD 0.34) were studied for a total of 54 sampling periods. Mean (SD) oxygen saturations were 97% (2.4) for blood samples, 96% (3.2) for the finger sensor, and 97% (2.8) for the forehead sensor. By Bland Altman analysis, bias ± precision was -1.16 ± 1.62% for the digit sensor and -0.36 ± 1.74% for the forehead sensor; root mean square differences were 1.93% and 1.70%, respectively. Bias and precision differed significantly between the 2 devices; the forehead sensor differed less from the blood sample.
• CONCLUSIONS In patients with low cardiac index, the forehead sensor was better than the digit sensor for pulse oximetry. (American Journal of Critical Care. 2007;16:146-152)

Monitoring oxygen saturation by using pulse oximetry (SpO₂) is a common method for assessing respiratory status in critically ill patients. With pulse oximeters, light-emitting diodes are applied to an area of the body with good local blood flow. Red and infrared light is shone through the blood-perfused tissue under the sensor and received by an opposing detector probe; the information is sent back to a signal-processing unit, or monitor, for calculation of oxygen saturation. Typically, the sensor is placed on a finger in adults or a foot in neonates. Pulse oximetry provides continuous, noninvasive information on the oxygenation status of patients and has greatly reduced the number of arterial punctures or arterial blood samples required for care.

Although pulse oximetry has advantages, several factors can adversely affect the performance of the devices. Movement by patients, low blood flow to the sensor area, and sensor adherence to the skin affect optimal performance. Since the introduction of pulse oximetry in the 1980s, improvements have been made to decrease the interference of these factors on continuous, reliable estimation of oxygen saturation. New adhesive materials and redesign of the sensor device placed against the skin have dramatically reduced problems with adherence and almost eliminated skin complications from sensor heat or reaction to adhesive materials. Improvements in sensor technology, particularly those
related to minimizing motion artifacts, have progressively improved the accuracy and reliability of the devices during the past 20 years.2-7

However, low blood flow conditions have continued to limit the usefulness of pulse oximetry. Clinical conditions that cause low blood flow states include low cardiac output due to hypovolemia or poor left ventricular function and peripheral vasoconstriction due to hypothermia (body temperatures <36ºC) or pharmacological effects from drugs used to treat hypotension and/or low cardiac output. Low blood flow to the sensor leads to an increase in incorrect SpO2 readings and in “drop out” readings, when the monitor cannot calculate an oxygen saturation with confidence and so does not provide a reading or indicates an inoperative situation.8-10 Generally, overcoming the limitations of pulse oximeters in low blood flow situations has been elusive.

New pulse oximeter sensors (Max-Fast, Nellcor Puritan Bennett Inc, Pleasanton, Calif) have an embedded memory chip in the sensor that contains specific calibration and operating characteristics unique to that sensor design.11 The incorporation of this unique sensor information into the sensor itself provides greater accuracy for a range of different sensor designs when the devices are connected to the same signal-processing unit or monitor for SpO2 monitoring. The reflectance sensor is designed for placement on the forehead just above the orbital area, where superficial blood flow is abundant12 (Figure 1). Unlike finger or foot sensors, which have the emitter and detector probes on opposing surfaces of the tissue bed, in reflectance sensors the emitter and detector probes are adjacent to each other.

In laboratory tests, the forehead sensors tracked SpO2 more accurately than did previous sensor designs.11,13-15 Of particular note, the forehead sensor was better than finger sensors in the presence of peripheral vasoconstriction, simulated in the laboratory by placing healthy volunteers in a cold environment and inducing hypothermia.13-15 The investigators13-15 hypothesized that the improved tracking of oxygen saturation with the forehead sensor is due to better tissue blood flow in the forehead area, which is less affected than peripheral finger sensor sites by thermoregulatory vasoconstriction.

Table 1

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Primary diagnosis</th>
<th>Secondary diagnosis*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory insufficiency</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Cardiac surgery</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Sepsis</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*Some patients had more than one secondary diagnosis.

Limited clinical studies16-20 have been performed with the forehead sensor. In 2 studies, researchers evaluated the performance of the sensor in critically ill children in stable condition19 and in adult anesthesia patients in stable condition.20 In 2 other studies,16,17 investigators compared forehead and finger sensors in

Figure 1 Max-Fast forehead pulse oximeter sensor centered above the eye with a soft headband to provide gentle pressure on the sensor device.

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patients with poor peripheral perfusion who were receiving ventilatory support, but reporting of study methods and results was limited. In another study, the signal quality of forehead and finger sensors was examined during prehospital emergency transport. In 53 patients in stable condition, forehead sensors were associated with significantly fewer false alarms and malfunctions than were finger sensors. The purpose of our study was to compare SpO2 readings obtained with the forehead sensor with SpO2 readings obtained with a traditional finger sensor in clinical situations in which low peripheral perfusion is common.

Materials and Methods

This study was conducted at Saint Thomas Health Services, a large community hospital in Nashville, Tenn. The study was approved by the institution’s investigational review board and was in compliance with federal guidelines for the conduct of human research.

Study Design

A method-comparison design was used to examine the agreement between 2 different SpO2 sensors (finger and forehead sensors) used for noninvasive monitoring of oxygen saturation and the clinical reference standard for oxygen saturation, arterial oxygen saturation (SaO2). Each subject served as his or her own control; measurements were obtained 3 different times within a 12-hour period. The primary dependent variable was the difference in oxygen saturation between the SaO2 clinical reference standard and the SpO2 obtained with each test sensor (finger and forehead sensors; difference = SpO2 - SaO2).

Sample

Subjects for this study were critically ill patients with low perfusion states. Patients were included if they were at least 21 years old but less than 85 years old, had pulmonary artery and arterial catheters in place, and had a cardiac index of 2.5 (calculated as cardiac output in liters per minute divided by body surface area in square meters). Patients were excluded if they had a left ventricular assist device; hand, finger, or forehead impediments that would preclude proper placement of the test sensors (eg, hand splinting, tape over the placement site); a requirement for Trendelenburg positioning, or excessive facial edema.

### Table 2

<table>
<thead>
<tr>
<th>Oxygen saturation</th>
<th>Range, %</th>
<th>Mean, %</th>
<th>SD, %</th>
<th>Bias, %</th>
<th>Precision, %</th>
<th>RMSD, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical reference standard (corrected) SaO2</td>
<td>88.2-99.9</td>
<td>97.39</td>
<td>2.43</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Finger SpO2 sensor</td>
<td>85-100</td>
<td>96.23</td>
<td>3.22</td>
<td>-1.16</td>
<td>1.62</td>
<td>1.93</td>
</tr>
<tr>
<td>Forehead SpO2 sensor</td>
<td>80-97</td>
<td>97.02</td>
<td>2.83</td>
<td>-0.36</td>
<td>1.74</td>
<td>1.70</td>
</tr>
</tbody>
</table>

* Calculated as cardiac output in liters per minute divided by body surface area in square meters.

Abbreviations: NA, not applicable; RMSD, root mean square of the differences; SaO2, oxygen saturation, arterial; SpO2, oxygen saturation as measured by pulse oximetry.

Forehead reflectance pulse oximeter emitter and detector probes are adjacent, whereas finger sensors are opposite one another.

Procedure

All patients who met the eligibility criteria for the study had 2 test sensors applied according to the manufacturer’s guidelines. The research finger-adhesive sensor (Max-N, Nellcor Inc, Pleasanton, Calif) was applied to the middle finger of the hand not being used for therapeutic pulse oximetry monitoring. Black photo tape was placed over the finger sensor to shield it from light interference. A disposable adhesive reflectance forehead sensor (Max-Fast, Nellcor Inc) was applied above the right orbital area on the forehead (Figure 1). An adjustable headband was placed over the forehead sensor to ensure gentle, consistent pressure on the sensor device.

Each sensor was connected to a study pulse oximeter unit (OxiMax N-595, software version 3.3.0, Nellcor Inc) and allowed to equilibrate for at least 15 minutes. Simultaneous readings from the 2 test SpO2 units were obtained at 3 different time points during a 12-hour period when samples for arterial blood gas analysis and cardiac output measurements were obtained for usual therapeutic care routines. Readings were obtained after verification of a 15-minute period of hemodynamic and respiratory stability, which was defined as no fluctuations.
in pulse or blood pressure greater than 10% of baseline values, no alterations in vasopressor agents greater than 10% of baseline rates per minute, administration of intravenous fluid and blood at a rate of less than 200 mL/h, no changes in ventilator settings, no endotracheal suctioning, and no disconnection from the ventilator.

The arterial blood sample for SaO2 analysis was obtained immediately after the finger and forehead SpO2 values were recorded. Samples for blood gas analysis were placed on ice and were analyzed within 30 minutes with a multiwavelength CO-oximeter (Series 800 Bayer Gas Instrument with CO-Oximetry, Bayer Corp, Tarrytown, NY), with bias and precision of -0.23 ± 0.3%, in the syringe mode for normal hemoglobin values. The CO-oximeter quality controls were run each day according to manufacturer’s guidelines.

Data Analysis
Pulse oximeters are calibrated to reflect the functional SaO2. Accordingly, before data analysis, clinical reference standard SaO2 values were calculated according to the following formula: \( \text{SaO}_2 = \left( \frac{\text{fractional oxyhemoglobin}}{1 - (\text{fractional carboxyhemoglobin} + \text{fractional methemoglobin})} \right) \times 100 \), where the fractional values are numbers between 0 and 1. This calculation converts the fractional oxyhemoglobin value measured and displayed by the CO-oximeter to functional oxygen saturation.

Data were summarized by using descriptive statistics. SpO2 values were compared with SaO2 values by using the method of Bland and Altman.24,25 Bias, precision, and root mean square of the differences were calculated to quantify the differences between the noninvasive SpO2 (finger and forehead sensors) values and the SaO2 values. The Student t test was used to determine if a significant difference in bias and precision existed between the 2 noninvasive SpO2 devices. The level of significance was set at .05.

Results
A total of 19 patients were studied for a total of 57 sampling periods. Because a reliable signal could not be obtained from the digit sensor during 3 sampling periods, only 54 samples were included for analysis. Primary and secondary diagnoses varied (Table 1); myocardial infarction was the most common diagnosis. The patients were 49 to 81 years old (mean 70.7, SD 8.9). Cardiac index values at the time oxygen saturation was measured ranged from 1.10 to 2.5 (mean 1.98, SD 0.34). Systemic vascular resistance ranged from 894 to 2069 dynes·s·cm⁻⁵ (mean 1344, SD 264.5). SaO2 values for the 54 samples ranged from 88.2% to 99.9%. Oxygen saturation values for the clinical reference standard and noninvasive sensors (finger and

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patient 016</th>
<th>Patient 016</th>
<th>Patient 019</th>
</tr>
</thead>
<tbody>
<tr>
<td>SaO2 (clinical reference standard), %</td>
<td>98.49</td>
<td>97.98</td>
<td>97.65</td>
</tr>
<tr>
<td>Finger SpO2 sensor, %</td>
<td>No reading</td>
<td>No reading</td>
<td>No reading</td>
</tr>
<tr>
<td>Forehead SpO2 sensor, %</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>SaO2 - SpO2 difference, %</td>
<td>1.51</td>
<td>2.02</td>
<td>2.35</td>
</tr>
<tr>
<td>Cardiac index*</td>
<td>2.1</td>
<td>2.1</td>
<td>1.9</td>
</tr>
<tr>
<td>Systemic vascular resistance, dyn · s · cm⁻⁵</td>
<td>1178</td>
<td>1238</td>
<td>1673</td>
</tr>
<tr>
<td>Finger edema, score†</td>
<td>2+</td>
<td>2+</td>
<td>1+</td>
</tr>
<tr>
<td>Body temperature, °C</td>
<td>37.1</td>
<td>36.9</td>
<td>37.3</td>
</tr>
<tr>
<td>Vasoactive drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart rate, beats/min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor</td>
<td>Dopamine</td>
<td>Dopamine</td>
<td>Norepinephrine</td>
</tr>
<tr>
<td>Finger sensor</td>
<td>No reading</td>
<td>No reading</td>
<td>No reading</td>
</tr>
<tr>
<td>Forehead sensor</td>
<td>99</td>
<td>99</td>
<td>112</td>
</tr>
</tbody>
</table>

* Calculated as cardiac output in liters per minute divided by body surface area in square meters.
† Scale ranges from 0 to +4.

Abbreviations: SaO2, oxygen saturation, arterial; SpO2, oxygen saturation as measured by pulse oximetry.

During low cardiac output, the forehead sensor had better agreement with SaO2 than did the finger sensor.
forehead) are shown in Table 2. Forehead reflectance sensors were well tolerated by patients and did not interfere with usual care. During 3 sampling periods, the SpO$_2$ monitor for the finger sensor did not display a value; consequently, these 3 sampling episodes were not included in the

Figure 2  Bland Altman graphs depicting the differences between the clinical reference standard SaO$_2$ value from the test sensor SpO$_2$ for the finger (A) and forehead (B) sensors.

Abbreviations: SaO$_2$, oxygen saturation, arterial; SpO$_2$, oxygen saturation measured by pulse oximetry.
Differences and limits of agreement between test sensors (finger, forehead) and the reference standard (arterial) oxygen saturation were bias ± precision -1.16 ± 1.62% and root mean square of the differences 1.93% for the finger sensor and -0.36 ± 1.74% and 1.70% for the forehead sensor (Table 2, Figure 2). The difference between the bias and precision of the 2 noninvasive SpO2 devices differed significantly ($t = -3.275$, $d = 53$, $P = .002$); the forehead sensor had less difference from the reference standard SaO2 than the finger sensor did.

**Discussion**

The new forehead SpO2 sensor had bias and precision values better than those of a traditional SpO2 finger sensor in patients with low cardiac output. These findings are similar to the results of laboratory studies in which poor peripheral perfusion was simulated by testing healthy volunteers under hypothermic body temperature conditions and to findings in patients with hypotension.

These findings are important to extending laboratory findings to a common clinical condition in critically ill patients: low cardiac output. The ability to have an additional monitoring site available for noninvasive monitoring of oxygen saturation will help clinicians provide better care to patients who have finger conditions or anatomical abnormalities, such as peripheral edema, excessive movement of an extremity, burns, and/or the presence of orthopedic devices, that can limit the effective use of peripheral sensors.

In addition, whereas no episodes of dropped values occurred with the forehead SpO2 sensor during the 57 sampling periods, 3 episodes of dropped values occurred with the finger sensor. The finding of superior performance in situations of low peripheral perfusion with the forehead sensor is similar to the results of laboratory studies and in brief clinical reports of this new technology. Improved function of the forehead sensor during low peripheral perfusion most likely is due to the lack of vasoconstrictor response in the blood vessels in the forehead area; blood vessels leading to finger sensors have a high vasoconstrictor response to certain physiological conditions such as low blood flow and cold ambient temperatures. These findings suggest that in clinical situations in which frequent or critical episodes of dropped signals occur with traditional finger sensors, the use of a forehead sensor may decrease these alarm conditions and improve continuous, noninvasive SpO2 monitoring.

Additional research is needed to determine the accuracy and performance of the forehead sensor in critically ill patients with abnormally low oxygen saturation. In our study, Sao2 was less than 95% in only 5 of 54 instances. Although limited laboratory and clinical studies of the performance of forehead sensors during hypoxemic states have indicated better performance with the forehead sensor than with finger sensors, additional clinical studies are needed to validate the performance of forehead sensors in critically ill hypoxemic patients with vasoconstriction.

**Conclusion**

The forehead SpO2 sensor is an acceptable alternative to finger sensors in situations of low cardiac output or when peripheral SpO2 signals are difficult to obtain. Further study is needed to determine if forehead SpO2 sensors perform better than finger sensors in low cardiac output states when hypoxemia is present and in other situations of low peripheral perfusion, such as hypothermia. Also, additional research could help determine whether forehead SpO2 sensors are faster than finger SpO2 sensors in detecting rapid changes in SaO2 that can occur with endotracheal suctioning, bronchospasm, and other sudden declines in pulmonary function.

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