The Accuracy and Response Characteristics of a Simplified Ear Oximeter*

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We evaluated the accuracy and speed of response of a newly available, lightweight, and relatively inexpensive ear oximeter (Biox II oximeter). The instrument was compared with another oximeter (Hewlett-Packard 47201A) under conditions of both steadily maintained and progressively increasing hypoxia induced in normal subjects by rebreathing. The new oximeter (Biox II), which can be operated in either a “normal” or “fast” response mode, as selected by a switch on the front panel, was evaluated in its “normal” mode during steady-state hypoxic conditions and in both “normal” and “fast” modes during progressive hypoxic conditions. The other oximeter (HP 47201A) was operated in its factory preset “normal” mode for all measurements. During steady-state hypoxia the relationship between oximeter arterial oxygen saturation (SaO₂) readings (y) and spectrophotometrically measured SaO₂ in samples of arterial blood (x) when SaO₂ exceeded 65 percent was as follows: for the new oximeter (Biox), y = 0.95x + 3.25 (r = 0.96); and for the other oximeter (HP 47201A), y = 1.03x – 2.31 (r = 0.94). Neither of these relationships differed significantly from the line of identity. During trials of progressive isocapnic hypoxia induced acutely in ten normal subjects, SaO₂ was measured continuously by both oximeters. With the new oximeter (Biox) operated in the “normal” mode, the relationship between values for SaO₂ from it (y) and the other oximeter (Hewlett-Packard) (x) was y = 0.85x + 12.91 (r = 0.93). When the new oximeter (Biox) was switched to its “fast” response mode, the relationship more closely approximated the line of identity such that y = 1.05x – 5.95 (r = 0.98). The response of the new oximeter (Biox II) to an in vitro step change in saturation followed a complex nonexponential function characterized by small initial changes in output signal with the greatest changes in output occurring during the latter portion of the response period. The 50 percent response times of the new oximeter (Biox II) were 5.65 seconds and 2.86 seconds in the “normal” and “fast” modes, respectively, by contrast to the 50 percent response time of 2.87 seconds for the other oximeter (H-P 47201A).

We conclude that the new oximeter (Biox II) demonstrated accuracy comparable to a more complex and expensive oximeter and had response characteristics that may be useful in clinical and laboratory settings.

Ear oximetry provides a noninvasive method for evaluating arterial oxygenation under both stable and rapidly changing conditions. Its use has been recommended as a method for monitoring the condition of patients in respiratory failure, allowing frequent changes in a ventilator’s settings without the need for repeated blood sampling.1 In sleep laboratories, ear oximetric studies have helped to define the syndrome of sleep apnea and have revealed previously unsuspected episodes of profound nocturnal hypoxemia in patients with chronic bronchitis.2–4 The ear oximeter is invaluable in detecting exercise-induced desaturation in patients with interstitial pulmonary disease in whom resting blood gas levels may be normal.4–6 Its use allows the precise prescription of supplemental oxygen during respiratory rehabilitation and improves the safety of invasive procedures such as fiberoptic bronchoscopy.4 Assessment of the ventilatory response to hypoxia in the laboratory is accomplished rapidly and safely when arterial oxygen saturation (SaO₂) is monitored continuously and noninvasively.6 Furthermore, the instruments can be used by health personnel without special skills or training.

The most widely available commercial ear oximeter (the Hewlett-Packard 47201A) is reliable, accurate, and easy to calibrate, but it is heavy and relatively expensive and has a cumbersome earpiece that is uncomfortable to wear for prolonged periods of time. Its ear probe is connected to the oximeter by a delicate fiberoptic cable which must be handled carefully to avoid damage. By contrast, the recently developed ear oximeter (Biox II; B.T. Inc.) is approximately one-quarter of the weight and half the price of the other instrument (Hewlett-Packard). The new oximeter has a lightweight earpiece that clips comfortably to the earlobe, without requiring a tight headband. The ear probe is connected to the oximeter with a simple, sturdy electrical cable. In light of these potential advantages, we evaluated the accuracy and practicability of the newer instrument and compared it to the other oximeter (Hewlett-Packard model 47201A), an instrument whose operating characteristics we have previously validated.9

Materials and Methods

Equipment

The new oximeter (Biox II) measures SaO₂ continuously by monitoring the transmission of two wavelengths of light through the vascular beds of the earlobe. The light emitters and sensors are
incorporated in a lightweight ear-probe assembly which may be clipped to the earlobe (Fig 1) or pinna. The temperature of the skin's surface is maintained at 37°C (±1°C) by a heater in the ear probe's tip. If arterial perfusion of the earlobe is insufficient for accurate estimation of saturation, a front-panel indicator is illuminated. A 2.4-meter cable conducts the ear-lobe assembly's electrical signal to the oximeter, where saturation is calculated and displayed digitally on the instrument's front panel. An analogue output is available for connection to an external recorder. Two operational modes can be selected via a switch on the front panel, (1) a "normal" mode in which the manufacturer's stated 95 percent response time is six seconds, and (2) a "fast" mode in which the 95 percent response time is approximately halved.

Subjects

Ten healthy volunteers (seven men and three women) aged 21 to 44 years were studied. All were free of cardiopulmonary disease, and most were laboratory and hospital personnel familiar with the experimental procedures. One subject was a deeply pigmented black and one a moderately pigmented Asian; the remainder were white. All gave informed consent for the study.

Steady-State Hypoxia

The calibration of the oximeter (HP 47201A) in daily use in our laboratory was first confirmed by comparison with SaO2 measured in samples of arterial blood collected during steady-state hypoxia. An evaluation was then made of the new oximeter (Biox II) using a similar protocol of steady-state hypoxia.

Isocapnic hypoxia was induced by a rebreathing technique, described in detail elsewhere. In brief, the subjects rebreathed from a 6-L bag containing an initial gas mixture of 24 percent oxygen and 76 percent nitrogen. During the rebreathing procedure, the inspired oxygen concentration was allowed to fall as a consequence of oxygen consumption. Steady-state hypoxia was maintained at several predetermined levels of SaO2 by introducing a low flow of oxygen into the rebreathing bag so that the fractional concentration of oxygen in the inspired gas was held constant. End-tidal carbon dioxide pressure was monitored continuously using an infrared carbon dioxide analyzer (Gould Godart Capnograph Mark III) and was held constant at a predetermined level by drawing gas from the rebreathing bag through a carbon dioxide-absorbing bypass using a variable speed pump (W. E. Collins). Outputs from the oximeter and carbon dioxide analyzer were recorded continuously on a strip-chart recorder (Hewlett-Packard 7404A).

For trials employing the usual oximeter (HP 47201A), the machine was standardized according to the manufacturer's instructions, and the ear probe was applied after the subject's ear had been cleaned with isopropyl alcohol and "arterialized" by vigorous rubbing for 30 seconds. The ear probe was in place for at least five minutes before rebreathing began. The oximeter (HP 47201A) was operated with the factory's preset internal jumper lead for response time in the "normal" position. For trials employing the new oximeter (Biox II), the same procedures were followed except for the standardization step. As indicated in the new oximeter's (Biox II) operating guide, the instrument did not require routine standardization before use; instead, its calibration was verified using two factory-preset, internal calibration points. For these steady-state trials, the new oximeter (Biox II) was operated in its "normal" response time mode.

During the induction of hypoxia, samples of arterial blood were drawn from an indwelling radial arterial line over 30 seconds or less and were rejected for analysis if subsequent review showed that the oximeter's recorded SaO2 varied more than ±1 percent during the sampling period. The samples of arterial blood, in heparinized glass syringes, were placed in ice immediately, and the SaO2 was determined within three hours on a spectrophotometer (Gilford model 240).

Progressive Hypoxia

To compare and contrast the two oximeters under conditions of rapidly changing SaO2, all subjects underwent the induction of progressive isocapnic hypoxia while SaO2 was monitored simultaneously by the two instruments. The ear was prepared as described previously by rubbing with isopropyl alcohol, and each instrument's ear probe was applied as outlined in the manufacturer's operating guide. The selection of right or left ear for application of the ear probes was made randomly in each subject. Progressive isocapnic hypoxia was induced using the rebreathing circuit as described previously for steady-state isocapnic hypoxia, except that no supplemental oxygen was added to the rebreathing bag during the trial.

Figure 2. Comparison of spectrophotometrically determined SaO2 in specimens of arterial blood (abscissa) and SaO2 measured by new oximeter (Biox II) (ordinate) during steady-state isocapnic hypoxia. Solid line is line of identity. Below SaO2 of 65 percent, new oximeter (Biox II) tended to overestimate SaO2.
Rebreathing was continued until the lowest SaO2 displayed by either instrument was 65 percent, usually about four to six minutes after the onset of rebreathing. The oximeters' outputs were recorded continuously on a strip-chart recorder for subsequent analysis. In all trials the usual oximeter (H-P 47201A) was operated with the factory's preset internal jumper lead for response time in the "normal" position. Comparison was made with the new oximeter (Biox II) in its "normal" and "fast" response modes, and these data were analyzed separately. Comparison of oximetric SaO2 readings was made at 30-second intervals, and the relationship between the instruments was determined using least-squares linear regression.

Response Times

To define the response characteristics of the new oximeter (Biox II), its analogue output signal was monitored during a sudden step change in saturation between its two internal calibration points (98.2 percent and 84.9 percent) as selected by a switch on the front panel. The output in both "normal" and "fast" modes was recorded and analyzed on a computer (Hewlett-Packard 9825A).

RESULTS

Steady-State Hypoxia

The relationship between the usual oximeter's (HP 47201A) SaO2 readings (y) and spectrophotometrically measured SaO2 (x) was linear for values of SaO2 greater than 65 percent, such that \( y = 1.03x - 2.31 \) (\( r = 0.94; n = 14 \)). The slope and intercept of this relationship were not significantly different (for both, \( p > 0.2 \)) from our previously published analysis of the instrument\(^a\) \( y = 0.99x - 1.52; r = 0.97 \) or from the line of identity.

For the new oximeter (Biox II), there was a linear relationship between oximetric readings for SaO2 (y) and spectrophotometrically measured values for SaO2 above 65 percent (x) defined by the equation, \( y = 0.95x + 3.25 \) (\( r = 0.96; n = 16 \)) (Fig 2). The slope and intercept of this relationship did not differ significantly from the line of identity (for both, \( p > 0.2 \)). When SaO2 was below 65 percent, the instrument tended to overestimate the SaO2 (Fig 2).

Progressive Hypoxia

With the new oximeter (Biox II) operating in the "normal" mode, the relationship between its readings for SaO2 (y) and those of the other oximeter (HP 47201A) (x) during progressive isocapnic hypoxia was \( y = 0.85x + 12.91 \) (\( r = 0.93 \)) (Fig 3). With the new oximeter (Biox II) operated in the "fast" mode, the relationship moved closer to the line of identity such that \( y = 1.05x - 5.95 \) (\( r = 0.98 \)) (Fig 4). In both operating modes the correlation was poorest at the lowest levels of oxygenation when SaO2 changed most rapidly during progressive hypoxia.

Response

The time response of the new oximeter (Biox II) to an in vitro step change in saturation is shown graphically in Figure 5 for both operational modes and is contrasted to the response of the other oximeter (HP 47201A), as determined previously.\(^b\) The response of the new oximeter (Biox II) was a complex nonexponential function which could not be defined readily in terms of a time constant. After an initial delay of 0.49 second in the "normal" mode and 0.33 second in the "fast" mode, the new oximeter (Biox II) moved slowly toward its new output value, accelerated late, and then decelerated abruptly before settling at the final output value without overshoot. We observed 50 percent response times of 5.65 seconds and 2.86 seconds in the "normal" and "fast" response modes, respectively, by contrast to the other oximeter's (HP 47201A) 50 percent response time of 2.87 seconds in the "normal" mode.
DISCUSSION

In a previous study, we have shown that by comparison to blood sampling, the usual oximeter (HP 47201A) accurately measures \( \text{SaO}_2 \) under conditions of either progressive or steady-state isocapnic hypoxia. The present data show that despite its smaller size and lightweight earpiece, the new oximeter (Biox II) showed comparable accuracy under these conditions when operated in the more appropriate of its available response time modes.

Under steady-state hypoxic conditions, when each level of \( \text{SaO}_2 \) was held constant for up to 30 seconds, both oximeters reflected accurately \( \text{SaO}_2 \) levels of 65 percent or greater measured spectrophotometrically in samples of arterial blood collected simultaneously; however, as changes in \( \text{SaO}_2 \) in hypoxic patients may be rapid, a clinically useful ear oximeter should also follow these changes promptly. Our method of inducing acute progressive isocapnic hypoxia results in rapid changes of \( \text{SaO}_2 \) similar in degree and time course to those seen in such clinical settings as sleep apnea. These test conditions may therefore be appropriate to verify the potential clinical usefulness of the instrument. Under these rapidly changing conditions, we have found that the new oximeter (Biox II), operated in its "fast" mode, showed accuracy comparable to the other oximeter (Hewlett-Packard 47201A) operated in its "normal" mode.

Operated in the "normal" mode, the new oximeter (Biox II) completed 95 percent of its response to a step change in 6.24 seconds. The corresponding time response for the other oximeter (Hewlett-Packard 47201A) operated in its "normal" mode was 9.83 seconds; however, the former instrument develops the greatest increment change late in its response time period, whereas the latter instrument follows a typical negative exponential response curve, making its greatest increment change at the onset of its response time. A more revealing comparison between the instruments is the 50 percent response time, which is 5.65 seconds and 2.86 seconds for the new oximeter (Biox II) operated in its "normal" and "fast" modes, respectively, and is 2.87 seconds for the other oximeter (Hewlett-Packard) operated in its "normal" mode. This similarity of the new oximeter's (Biox II) (fast mode) and the other oximeter's (HP 47201A) (normal mode) in vitro 50 percent response times was reflected by the improved correlation between instruments of \( \text{in vivo} \) \( \text{SaO}_2 \) measurements made during progressive hypoxia when the new oximeter (Biox II) was operated in the more rapid of its two response modes. It appears, therefore, that when used clinically in situations when rapid or transient changes in \( \text{SaO}_2 \) may be expected, the new oximeter (Biox II) appears to be more useful when operated in its "fast" mode.

Following the manufacturer's instructions, we found the new oximeter (Biox II) was simple to operate and could be mastered quickly by relatively untrained personnel. The lightweight ear probe was easily fitted to all subjects and was well tolerated. The improved patient acceptance of this ear probe as compared to other types previously available may be an advantage when prolonged observation, such as during overnight sleep studies, is required; however, the clip-on design of this ear probe has a potential disadvantage. If the spring tension is sufficiently high, the flow of blood may be occluded, and accurate readings will not be obtained (a condition which should be signalled by a low-flow alarm on the front panel). In our experience recorded herein, with adult subjects in the laboratory, and in subsequent clinical experience with both stable and critically ill adult patients, this problem has not been observed. Further observations in the pediatric population and in patients with low cardiac output are warranted.

In a previous study of the usual oximeter (HP 47201A), its accuracy was unaffected by skin pigmentation. During our present study, the new oximeter (Biox II) showed comparable accuracy in pigmented subjects. The accuracy of the other oximeter (HP 47201A) is known to be adversely affected by elevated concentrations of carboxyhemoglobin and by jaundice. The new oximeter (Biox II) remains to be evaluated in the presence of these potentially confounding factors.

In the past decade, our laboratory has used ear oximetry for both research and clinical purposes and has had the opportunity to evaluate several commercially available ear oximeters. The earliest instruments (such as the Waters XP-350 and Waters 0-1100) were cumbersome, difficult to calibrate, and sometimes nonlinear, and employed uncomfortable ear probes that were difficult to apply. The latest generation of
oximeters, an example of which has been evaluated in this study, make available at lower cost a machine which is simple to operate and is well tolerated by subjects. Despite its smaller size and ease of operation, its accuracy is comparable to more expensive instruments that measure up to eight wavelengths of transmitted light. Accurate, continuous noninvasive monitoring of arterial oxygenation in patients with cardiorespiratory disorders is now feasible at a cost that should encourage its more widespread use.

REFERENCES
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