EFFECT OF ANEMIA ON PULSE OXIMETER ACCURACY AT LOW SATURATION

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Severinghaus JW, Koh SO. Effect of anemia on pulse oximeter accuracy at low saturation.

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ABSTRACT. A retrospective evaluation of simultaneous tests of oximeters of various manufacturers in volunteer subjects disclosed greater errors at low saturations in subjects with low hemoglobin (Hb) concentrations. Forty-three pulse oximeters of 12 manufacturers studied over a period of 10 months showed that, at a mean arterial oxygen saturation (SaO₂) level of 54.5%, as Hb concentration fell, average pulse oximeter (SpO₂) bias increased approximately linearly from 0 at Hb > 14 g/dl to about -14% at 8 < Hb < 9 g/dl. At SaO₂ = 53.6%, the mean bias $(SaO_2 - SpO_2)$ of 13 oximeters of 5 manufacturers averaged -15.0% (n = 43) in a subject with Hb = 8 g/dl, but -6.4% (n = 390) in nonanemic subjects. The additional bias in the anemic subject increased with desaturation. It was 0.13% at $SaO_2 = 98.5\%$ (n = 13), -1.31% at 87.5% (n = 38), -2.71% at 75.1% (n = 38), -5.18% at 61.3% (n = 26), and -9.95% at 53.6% (n = 41); n is the product of the number of oximeters and number of tests in each saturation range. The instruments that showed the greatest errors at low saturations in nonanemic subjects also showed the greatest additional errors associated with anemia (the range between manufacturers of anemic incremental error at about 53% being from -3.2 to -14.5%) and conformed well to the relationship bias (anemic) = $1.35 \times \text{bias}$ (normal) -8.18% (r = 0.94; S_{y x} = 3.3%). The error due to anemia was zero at 97% SaO2 and became evident when SaO2 fell below 75%.

KEY WORDS: Measurement techniques: pulse oximetry. Blood: anemia. Equipment: pulse oximeters. Oxygen: saturation. Hypoxia.

The effect of anemia on the accuracy of pulse oximetry at varying levels of arterial oxygen saturation (SaO₂) has not been previously studied in humans. Using a Nellcor N-100 mounted on the dog tongue, when hematocrit was diluted to less than 10% Lee et al [1] noted a bias of $-5.4 \pm 7.1\%$ at normal levels of SaO₂. Desaturation was not investigated.

In the course of studies of the accuracy of pulse oximeter saturation (SpO_2) readings at low SaO_2 values in normal volunteer subjects [2,3], it became evident that greater bias was seen at low saturation in subjects with low hemoglobin (Hb) concentrations. Review of the data disclosed 4 sets of studies, 10 subjects per set, in which 1 or more of the subjects had Hb concentrations less than 11 g/dl. Forty-three pulse oximeters of 12 manufacturers were studied in these 40 subjects. We retrospectively examined the relationship among Hb concentration, pulse oximeter bias, and SaO_2 in these studies.

METHODS

chaus, 1386 HSE, Box 0542, CA 94143-0542. A method of inducing rapid arterial oxygen desaturation to a stable plateau lasting about 30 seconds in nor-

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mal volunteer subjects has been used for several years in studies of pulse oximeters of 14 manufacturers [2,3]. The studies were approved by the Committee on Human Research and the subjects signed informed consent. The inspired oxygen concentration was manually adjusted in response to saturation computed breath-bybreath from mass spectrometric end-tidal oxygen and carbon dioxide tensions. An arterial sample was drawn from an indwelling radial arterial catheter immediately before sudden reoxygenation. Oximeter averaging times ranged from 3 to 8 seconds. The recorded end plateau values of each oximeter were measured later on a graphic computer screen. A test set consisted of 10 subjects; each was studied 3 times at each of 4 hypoxic levels, nominally 86, 74, 62, and 50% SaO₂, plus a single normal (air) point. In each set of studies reported here, 8 to 13 instruments of 5 manufacturers were tested simultaneously. Studies of 43 oximeters from 12 manufacturers are included. Most probes were mounted on fingers, a few on ears or forehead.

RESULTS

In Figure 1, the bias (mean \pm SD) of 13 oximeters of 5 manufacturers is shown for 1 anemic and 9 nonanemic subjects in one set. For the 9 normal subjects, there were 22 to 30 readings per oximeter at each SaO_2 value; in the anemic subject, there were 2 to 4 readings for each point for each of the 13 oximeters, except below 60% SaO₂, where 2 oximeters (Ohmeda finger) uniformly defaulted to zero on the anemic subject. Below 80%, anemia approximately doubled the error. No significant error was detected at normal SaO2 values. Figure 2 displays the incremental error due to anemia for each of the instruments. One oximeter (Kontron ear probe) read about 3% lower in the anemic subject than in the normal subjects independent of SaO₂, except near 60%, while all other instruments erred increasingly as SaO₂ fell. The mean incremental anemic error was -10%SpO₂ at 53% SaO₂. Figure 3 indicates that at about 53% SaO₂, the bias of each oximeter with anemia was correlated (r = 0.94) with its bias in normal subjects, the anemic bias ranging from -3 to -29% and the nonanemic bias ranging from +3 to -15%.

In another set, 1 anemic subject with an Hb value of 10.5 g/dl was studied with 13 oximeters. Four data points were obtained at a mean SaO₂ of 45.6 \pm 2.7% and compared with 17 samples in the 9 nonanemic subjects in that group at a mean SaO₂ of 47.3 \pm 2.0%. The mean error in these 13 instruments in the 9 nonanemic subjects was +3.12% (n = 211), while in the anemic subject the error was -0.84% (n = 53). The incremental error attributed to anemia was computed to be

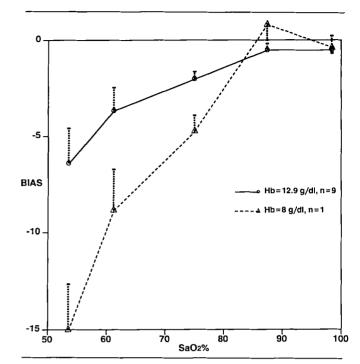


Fig 1. Bias (mean \pm SD) of 13 pulse oximeters (5 manufacturers) as a function of arterial oxygen saturation (SaO₂) in 9 nonanemic volunteers, compared with the same instruments tested in 1 subject with a hemoglobin (Hb) value of 8 g/dl. Anemia approximately doubled the bias already present at all tested levels below 80% SaO₂.

 $-3.96 \pm 4.69\%$, which was significant (P < 0.01). The range of anemic incremental error varied between instruments from +3.1 to -11.8%.

Figure 4 presents the relationship between the Hb concentration and the bias and its standard deviation, obtained by averaging all 43 oximeters of 12 manufacturers tested over 9 months in the 4 sets of 10 subjects each, in which significantly anemic subjects were included.

DISCUSSION

The effect of anemia on pulse oximeter accuracy at low saturation is difficult to address prospectively, since severely anemic subjects would not be considered suitable candidates for such tests. At best, only anecdotal evidence can be provided by the occasional patient who is both anemic and hypoxic. The anemic subjects reported here were not known to be anemic until after testing when the data from the blood oximeter (Radiometer OSM3) was examined. Hb concentration is not used in any of the calculations in the study and was recorded only incidentally. It might be thought surprising that no unusual responses to low saturation were seen in anemic

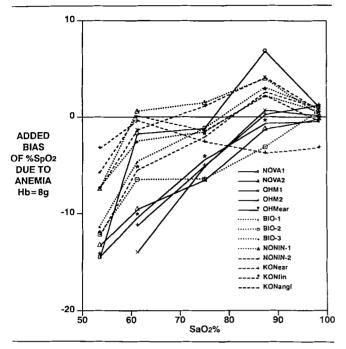


Fig 2. The incremental bias attributable to anemia in each of the 13 instruments tested, obtained as the differences of the mean bias at each saturation level in an anemic subject versus those in 9 nonanemic subjects. Two Ohmeda finger oximeters defaulted to zero when arterial oxygen saturation (SaO_2) fell below 60% in the anemic subject. SpO₂ = SaO₂ measured with a pulse oximeter; Hb = hemoglobin; NOVA = Novametrix; OHM = Ohmeda; BIO = Biochem; KONear = Kontron (Roche) ear probe; KONfin = Kontron finger probe. KONangl is a non-flexible angle probe.

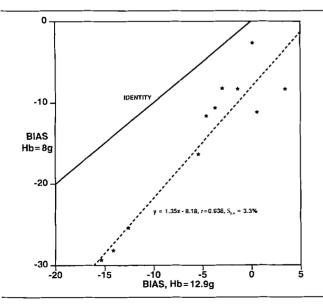


Fig 3. At an arterial oxygen saturation (SaO_2) of around 53%, bias due to anemia is proportional to bias at normal hemoglobin (Hb) concentration. Each asterisk represents the mean of a single oximeter's responses in the 9 nonanemic subjects plotted against its mean bias in the subject with Hb = 8 g/dl.

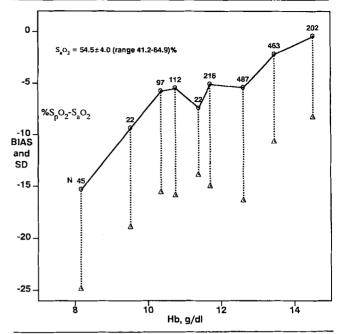


Fig 4. The relationship of hemoglobin (Hb) concentration to bias (mean \pm SD) of 43 pulse oximeters from 12 manufacturers in 40 subjects at a mean arterial oxygen saturation (SaO₂) of around 54.5%. Data were taken from 4 sets of 10 subjects, among whom one or more proved to be anemic. The oximeters studied differ from point to point. SpO₂ = SaO₂ measured with a pulse oximeter.

subjects. Indeed, the woman with an Hb of 8 g/dl had been studied several months earlier when her Hb concentration was 10.5 g/dl. She was specifically asked after the second study about symptoms but reported none, with no amnesia or loss of consciousness at the lowest saturation levels.

The incremental error associated with low Hb concentrations at very low saturations varied over a fivefold range between oximeters. Furthermore, those oximeters that were found to be most accurate at low saturations in nonanemic subjects showed the least additional bias in anemia. This suggests that correction of bias at low saturations in normal subjects might also reduce the bias due to anemia.

The cause of this error with anemia is not evident. In clear Hb solutions used in laboratory multiwavelength oximeters, no correction for Hb concentration is required in the calculation of saturation. The negative bias of many pulse oximeters at low saturations has been attributed by the inventor of pulse oximetry (Aoyagi T, personal communication, 1986) to multiple scattering of the photons as light diffuses through tissue and whole blood. We may also speculate that, as falling saturation causes less red light to penetrate the tissue, the automatic increase of red light-emitting diode (LED) intensity built into many oximeters may lower its wavelength (by increased heating). The absorption of red light by desaturated Hb increases rapidly as wavelength decreases, causing an apparent fall in saturation. Some instruments have programmed compensation for this shift of wavelength, but the correction must vary with tissue thickness, Hb concentration, and perhaps with time of heating of the LED.

It is fortunate that these errors are protective, in the sense that they overestimate the degree of desaturation in anemic subjects where the harm could be greatest.

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