

Accuracy of pulse oximetry in pigmented patients

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Objective. Prospective assessment of the accuracy of three pulse oximeters and two probe sites in darkly pigmented critically ill patients under clinical conditions.

Patients and methods. One hundred consecutive, darkly pigmented critically ill adult patients with arterial lines *in situ* were studied. Patients were excluded if the haemoglobin concentration was less than 7 g/dl and carboxyhaemoglobin or methaemoglobin levels exceeded 2%. Pigmentation was objectively quantified with a portable EEL reflectance spectrophotometer (Evans Electroselenium Company, Diffusion Systems Limited, London). Reflectance was measured at nine wavelengths.

Results. The degree of pigmentation as measured by percentage reflectance closely matched that of a control group of black Africans from a pigmentation study. The limits of agreement (2.6% to 5.8%), precision and bias values between pulse oximeter and co-oximeter readings fell within a narrow range. The 95% confidence intervals of the limits of agreement reflected a small variation in the difference between pulse oximeter and co-oximeter readings. These small differences were not clinically significant in the pigmented patients who were enrolled in the study.

Conclusion. The accuracy of pulse oximetry is not adversely affected by skin pigmentation, and it remains a useful oxygenation monitoring device in darkly pigmented patients.

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Continuous assessment of arterial oxygenation is important in the management of anaesthetised and critically ill patients.¹ Arterial blood gas analysis is reliable, but it is an invasive procedure and provides intermittent information only.² Continuous determination of the arterial oxygen

saturation (SaO₂) of haemoglobin by pulse oximetry is now a minimum monitoring requirement in the operating theatre³ and is becoming routine in the intensive care unit (ICU)⁴ as well as special care areas outside.⁵ Patient safety is enhanced by pulse oximetry⁶ as it continuously and accurately reflects arterial oxygen saturation, warning of dangerous desaturations⁷⁻⁸ which are associated with adverse outcome.⁵

In our ICU pulse oximetry is a routine monitoring tool. The important question is whether pigmentation of the skin adversely affects accuracy of pulse oximeter saturation readings. The opinion that it does is supported by some published findings.⁹⁻¹¹ Conversely, others^{12,13} could not demonstrate any loss of accuracy due to skin pigmentation. All these studies included small numbers of black patients only and no reliable conclusions can be made from them.

In view of the uncertainty in the clinical data⁹⁻¹³ we prospectively investigated the accuracy of three pulse oximeters and two probe sites in darkly pigmented critically ill patients under clinical working conditions.

Patients and methods

Approval for the study was obtained from the hospital and university Ethics Committees. One hundred consecutive darkly pigmented critically ill adult patients with arterial lines *in situ* were studied. Patients were excluded if haemoglobin levels were less than 7 g/dl¹⁴ and if carboxyhaemoglobin or methaemoglobin levels exceeded 2%.¹⁵ The study was performed in a multidisciplinary ICU under standard working conditions.

Patients were selected when they subjectively appeared darkly pigmented. Pigmentation was then objectively quantified with a portable EEL reflectance spectrophotometer (Evans Electroselenium Company, Diffusion Systems Limited, London). Reflectance was measured at nine wavelengths (426, 465, 485, 515, 545, 575, 595, 655 and 685 nm). The measurement was done on the inner surface of the upper arm and the volar aspect of the finger. The former was done to measure natural pigmentation, not darkened by sun-tanning.¹⁶

Three pulse oximeters, the Sirmed S100e (Sirmed Co., Bothwell, Wash., USA), the Nihon Koden (Nihon Koden Corp., Tokyo) and Ohmeda 3740 (Ohmeda, Louisville, Colo., USA) were compared with co-oximetry¹⁷ (Instrumentation Laboratories IL482 Co-oximeter System, Lexington, Mass., USA).

A finger probe from each pulse oximeter and an ear probe from the Ohmeda were applied and 5 minutes were allowed for stabilisation of pulse oximeter readings. Once adequate signals were recorded, an arterial blood sample was taken for immediate co-oximetry. At the same time the four pulse oximeter readings were recorded.

Bias (mean of differences) and limits of agreement (accuracy), defined as mean of differences \pm 2 SD, between pulse oximeter and co-oximeter SaO₂,¹⁸ 95% confidence intervals (CIs) for bias and accuracy, and precision (standard deviation of the differences)¹⁹ were determined for each of the pulse oximeters.

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Results

The degree of pigmentation as judged by percentage reflectance (Table I) closely matched that of a control group of pigmented volunteers from an albinism study.²⁰ Our patients had a mean reflectance of 19.9 compared with 18.4 for the pigmented volunteers.²⁰

Table I. Comparison of mean percentage reflectance at nine wavelengths in patients with albinism, a random group of pigmented volunteers and study patients

| | Mean | SD |
|----------------------|-------|------|
| Albinism | 52.3* | 4.5* |
| Pigmented volunteers | 18.4* | 5.8* |
| Study patients | 19.9 | 5.6 |

* Adapted from Roberts et al.²⁰

Co-oximeter SaO₂ ranged from 87.8% to 99.2%, and median saturation was 96%. Five co-oximeter readings fell below an SaO₂ of 92%. Pulse oximeter saturations varied between a minimum of 86% and a maximum of 100% (Table II). The limits of agreement (Figs 1 - 4) between co-oximeter and pulse oximeter for Simed (2.6% to 5.0%), Nihon Kodon (4.1% to 5.8%), Ohmeda finger (3.4% to 4.5%), and Ohmeda ear (3.8% to 5.8%) are within clinically acceptable bounds. The 95% CIs for upper and lower limits of agreement (a measure of variation around these boundaries of accuracy) fall within a narrow range (Table III). This suggests that the variation of the differences is small.

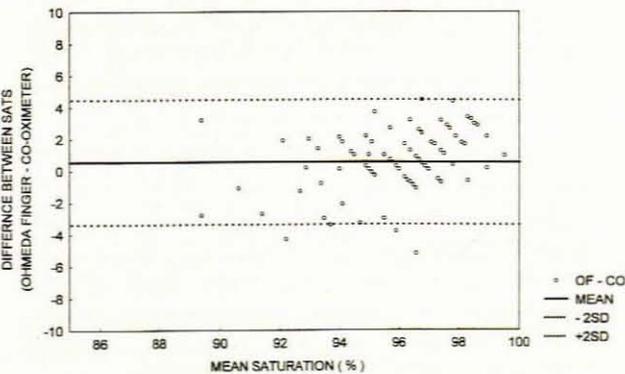


Fig. 1. Plot of differences against means (Simed : co-oximeter).

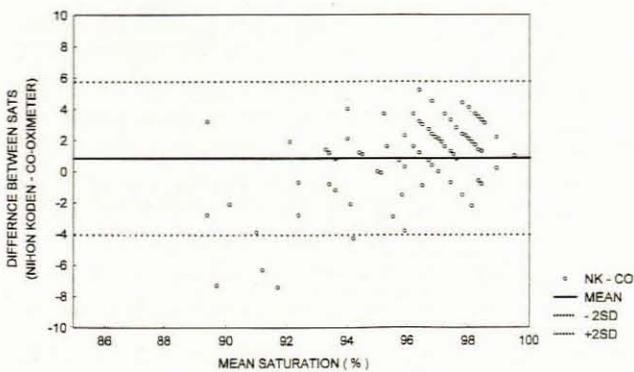


Fig. 2. Plot of differences against means (Nihon Kodon : co-oximeter).

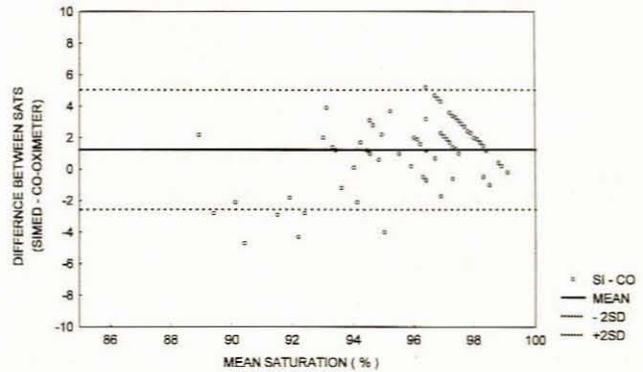


Fig. 3. Plot of differences against means (Ohmeda finger : co-oximeter).

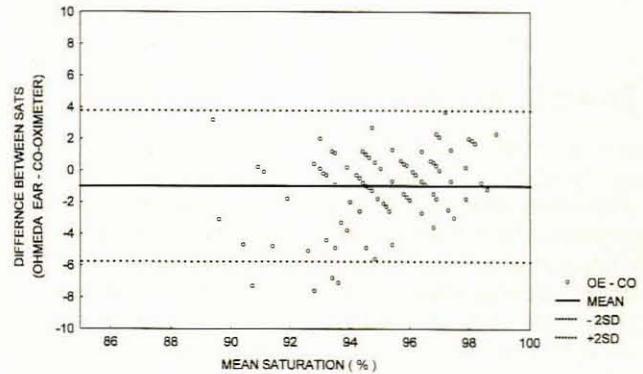


Fig. 4. Plot of differences against means (Ohmeda ear : co-oximeter).

Table II. Summary statistics, arterial oxygen saturation

| Device | Min. (%) | Max. (%) | Median (%) | Quartiles |
|---------------|----------|----------|------------|-------------|
| Co-oximeter | 87.8 | 99.2 | 96 | 94.5 : 96.9 |
| Simed | 88 | 99 | 98 | 96 : 99 |
| Nihon Kodon | 86 | 100 | 97 | 95 : 99 |
| Ohmeda finger | 88 | 100 | 96 | 95 : 98 |
| Ohmeda ear | 87 | 100 | 95 | 93 : 96 |

Table III. CIs for the limits of agreement

| Device | Lower limit of agreement 95% CI | Upper limit of agreement 95% CI |
|---------------|---------------------------------|---------------------------------|
| Simed | -3.2 - -1.9% | 4.4 - 5.7% |
| Nihon Kodon | -4.9 - -3.2% | 4.9 - 6.6% |
| Ohmeda finger | -4.1 - -2.7% | 3.8 - 5.2% |
| Ohmeda ear | -6.6 - -4.9% | 3.0 - 4.6% |

Precision and bias for each pulse oximetry method was evaluated (Table IV). The precision of Simed finger (1.9%) and Ohmeda finger (2.0%) probes is within the 2% points of manufacturer specification. Precision values for Nihon Kodon finger and Ohmeda ear probes (2.4% for both) were slightly more than manufacturer specification.

The bias ranged between -1.0% for Ohmeda ear and 1.2% for Simed finger probes.

The 95% CIs for these biases were 0.9 - 1.6 and -1.5 - -0.5, respectively. Simed, Nihon Kodon, and Ohmeda finger

probes tended to record slightly higher and Ohmeda ear slightly lower saturations when compared with co-oximetry. These differences are small and are therefore not significant on the clinical level in pigmented patients.

Table IV. Precision of pulse oximeter in darkly pigmented patients versus manufacturer specification

| Manufacturer reference | Measured precision (range 87.8 - 99.2%) | Measured bias (95% CI) | Manufacturer precision (% sat. range) |
|-----------------------------|---|------------------------|---------------------------------------|
| Simed ²³ | 1.9 | 1.2 (0.7 - 1.6%) | 2.0 (70 - 99%) |
| Nihon Koden ²⁴ | 2.4 | 0.8 (0.4 - 1.3%) | 2.0 (80 - 100%) |
| Ohmeda finger ²⁵ | 2.0 | 0.6 (0.2 - 0.9%) | 2.4 (60 - 100%) |
| Ohmeda ear ²⁵ | 2.4 | -1 (-1.5 - -0.5%) | 2.4 (60 - 100%) |

Discussion

In most clinical studies no deliberate wide variations of SaO₂ are introduced. Therefore a good correlation does not imply an accurate measurement and a poor correlation does not imply an inaccurate measurement.²¹ For these reasons regression analysis has been shown to be inadequate to quantify error in accuracy when testing pulse oximeters. When comparing different measurement techniques (in this study co-oximetry), Bland and Altman^{15,22} recommend calculating the mean and standard deviation of the difference between the two methods of measurement. In their critical reviews of published pulse oximetry studies, Tremper and Barker¹⁹ and Severinghaus and Kelleher²¹ have recommended this method to determine pulse oximeter accuracy by measuring precision and bias. The bias will show an overestimate or underestimate of the method relative to the measurement standard, and the precision will represent the variability or the random error.¹⁹

Most manufacturers claim that their pulse oximeters are accurate to within 2% (SD) over the range of 70% to 100% saturation.^{19,23-25} The accuracy demonstrated in this study compares favourably with that claimed by the manufacturers of the pulse oximeters tested (Table IV) and accuracy reported in the literature. This degree of accuracy is considered more than sufficiently precise for most clinical purposes.²¹

Skin pigmentation should not influence pulse oximeter readings, since melanin absorbs a constant fraction of the transmitted light.^{11,15} The pulse oximeter uses only pulsatile absorption data. The pulsatile or AC component is then analysed and the constant or DC component of the transmitted light is subtracted from the total transmitted light. The height of the AC component is reduced by non-pulsatile absorption during transmission. This is then compensated for by division of the AC component of the transmitted intensity by the DC component to give the corrected AC signal. The latter parameter is sometimes called the pulse-added absorbance.¹⁹ The pulse oximeter then calculates the ratio of these pulse-added absorbances and plots it on a calibration curve to estimate the arterial oxygen saturation. These curves are based on data obtained from experimental studies in human volunteers.¹⁹

Detecting marginally low saturations is of clinical importance.⁹ In our study pulse oximeter readings at SaO₂ less than 92% tended to be lower than co-oximeter values. A few measurements also fell below 2 SD (Figs 1 - 4). This seems to suggest reduced reliability of pulse oximeter readings for all four devices at these lower limits of saturation. However, there is an insufficient number of values at this range to make any conclusive statement. Simed, Nihon Koden and Ohmeda finger probes tended to record slightly higher and Ohmeda ear slightly lower saturations when compared with co-oximetry. The 95% CIs for biases lay between -1.5% and -1.6%. These differences are small and therefore are not significant on the clinical level in pigmented patients.

The study was done on fairly stable patients and a similar study should confirm the agreement between co-oximetry and pulse oximetry in pigmented patients with lower saturations as well as with pulse oximeters from other manufacturers.

Conclusion

Pulse oximeter accuracy is not adversely affected by skin pigmentation and remains a useful oxygenation monitoring device in darkly pigmented patients.

REFERENCES

- Yelderman M, New W jun. Evaluation of pulse oximetry. *Anesthesiology* 1983; **59**: 349-352.
- Niehoff J, DelGuercio C, LaMorte W, et al. Efficacy of pulse oximetry and capnometry in postoperative ventilatory weaning. *Crit Care Med* 1988; **16**: 701-705.
- Barker SJ. Role of pulse oximetry in the ICU. *Chest* 1993; **104**: 330-331.
- Cohen NH. Monitoring the respiratory system in the ICU: what works and what doesn't. American Society of Anesthesiologists 1993 Annual Refresher Course Lectures, No. 244, pp. 1-7.
- Moller JT, Pedersen T, Rasmussen LS, et al. Randomized evaluation of pulse oximetry in 20 802 patients: I. Design, demography, pulse oximetry failure rate, and overall complication rate. *Anesthesiology* 1993; **78**: 436-444.
- Moller JT, Johannessen NW, Espersen K, Ravlo O, Pedersen BD, Jensen PF. Randomized evaluation of pulse oximetry in 20 802 patients: II. Perioperative events and postoperative complication. *Anesthesiology* 1993; **78**: 445-453.
- Bowton DL, Scuderi PE, Haponik EF. The incidence of effect on outcome of hypoxemia in hospitalized medical patients. *Am J Med* 1994; **97**: 38-46.
- Scuderi PE, Bowton DL, Anderson RL, Prough DS. Pulse oximetry: would further technical alterations improve patient outcome? *Anesth Analg* 1992; **74**: 177-180.
- Cecil WT, Thorpe KJ, Fibuch EE, Tuohy GF. A clinical evaluation of the accuracy of the Nellcor N-100 and the Ohmeda 3700 pulse oximeters. *J Clin Monit* 1988; **4**: 31-36.
- Ries AL, Farrow JT, Clausen JL. Accuracy of two ear oximeters at rest and during exercise in pulmonary patients. *Am Rev Respir Dis* 1985; **132**: 685-689.
- Cahan C, Decker MJ, Hoekje PL, Strohl KP. Agreement between noninvasive oximetric values for oxygen saturation. *Chest* 1990; **97**: 814-819.
- Saunders NA, Powles ACP, Rebuck AS. Ear oximetry: accuracy and practicability in the assessment of arterial oxygenation. *Am Rev Respir Dis* 1976; **113**: 745-749.
- Gabrielczyk MR, Buist RJ. Pulse oximetry and postoperative hypothermia: an evaluation of the Nellcor N-100 in a cardiac surgical intensive care unit. *Anaesthesia* 1988; **43**: 402-404.
- Lee S, Tremper KK, Barker SJ. Effects of anemia on pulse oximetry and continuous mixed venous saturation monitoring in dogs. *Anesthesiology* 1991; **75**: 118-122.
- Ralston AC, Webb RK, Runciman WB. Potential errors in pulse oximetry: III: Effects of interference, dyes, dyshaemoglobins and other pigments. *Anaesthesia* 1991; **46**: 291-295.
- Kromberg JGR. A genetic and psychosocial study of albinism in Southern Africa. Ph.D. thesis, University of the Witwatersrand, Johannesburg, 1985.
- Varon AJ. Methemoglobinemia and pulse oximetry. *Crit Care Med* 1992; **20**: 1363-1364.
- Bland MJ, Altman DG. Statistical methods of clinical measurement. *Lancet* 1986; **1**: 307-310.
- Tremper KK, Barker SJ. Pulse oximetry. *Anesthesiology* 1989; **70**: 98-108.
- Roberts DF, Kromberg JGR, Jenkins TJ. Differentiation of heterozygotes in recessive albinism. *J Med Genet* 1986; **23**: 323-327.
- Severinghaus JW, Kelleher JF. Recent developments in pulse oximetry. *Anesthesiology* 1992; **76**: 1018-1038.
- Altman DG, Bland JM. Measurement in medicine: the analysis of method comparison studies. *Statistician* 1983; **32**: 307-317.
- Simed S100e Pulse Oximeter Operation Manual (Document No.4015002), Oct 1990: p. 44.
- Nihon Koden Corporation Operation Manual (Bedside monitor model BSM 8500.05 J/K), Oct 1988: p. 14.9.
- Ohmeda Product Information Manual (No. 1125/311), 1991: pp. A1-A2.

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