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Evaluation of Biox IIA ear oximeter

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ABSTRACT Arterial blood gas tensions, pH, and carboxyhaemoglobin were measured on 322 occasions in 165 patients and the actual oxygen saturation of the haemoglobin (Sao_2) was compared with the ear oxygen saturation (S_EO_2) recorded during the arterial sampling with a Biox IIA ear oximeter. The overall agreement between S_EO_2 and Sao_2 was good, with a mean difference in saturation (S_EO_2–Sao_2) of + 1.5% (SD 3.0). The difference in saturation remained similar at all levels of arterial saturation observed and was unaffected by carboxyhaemoglobin concentration. On four occasions (1% of readings), however, S_EO_2 and Sao_2 differed by more than 10% and such occasional errors might be misleading in clinical practice.

The measurement of arterial oxygenation by ear oximetry has proved extremely useful; but the ear oximeter hitherto most widely used, the Hewlett Packard 47201A,[1] which operated on eight wavelengths, is no longer commercially available. An alternative, the Biox IIA ear oximeter, is available but it operates on two wavebands only. A previous study has compared these two oximeters directly;[2] but the true accuracy of the Biox IIA ear oximeter can be assessed only by direct comparison with the saturation of arterial blood, and this has been done only with small numbers of samples.[2–4] We have undertaken a comparison of oxygenation assessed by the Biox IIA and arterial oxygen saturation in a large series and have studied the effects of carboxyhaemoglobin on the accuracy of the ear oximeter.

Methods

We compared the saturation measured by the ear oximeter with that measured in simultaneously sampled arterial blood. Ear oxygen saturation was recorded by one of two Biox IIA oximeters (hereafter called Biox A and Biox B). The ear probe was attached after intense rubbing of the ear with a gauze swab and was then allowed to stabilise for three minutes. Thereafter arterial blood was sampled by direct puncture and withdrawn over 10–20 seconds. The Biox reading over this period was recorded if stable to ± 1%. Arterial blood was analysed by an ABL-2 blood gas analyser (Radiometer, Copenhagen) and carboxyhaemoglobin measured with an IL 282 CO-Oximeter (IL UK Ltd, Warrington). The shift in the oxyhaemoglobin affinity curve resulting from the presence of different carboxyhaemoglobin concentrations was calculated[5] and the actual oxygen saturation of the available haemoglobin was then calculated on the basis of the patient's arterial oxygen tension (Pao_2). The Biox ear oximeter readings (S_EO_2) were compared with actual arterial oxygen saturation (Sao_2).

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Results

Three hundred and twenty two comparisons of arterial saturation with ear oximeter readings were made in 165 patients. The mean arterial oxygen saturation was 88.5% (range 52–99%) and the mean carboxyhaemoglobin 3.8% (range 0.8–13.8%). Two hundred and forty three measurements were made with Biox A and 79 with Biox B. Neither the slopes nor the intercepts of the regression lines for ear oximeter reading against Sao_2 were different for Biox A and Biox B. The two sets of results therefore were combined (figure) and overall the Biox ear oximeters gave the relationship

$$S_EO_2 = 0.890\ (Sao_2) + 11.208$$

The relationship between S_EO_2 and Sao_2, when expressed as the mean difference (S_EO_2–Sao_2), changed little as Sao_2 decreased (table). The ear oximeter readings tended to be slightly higher than the actual arterial oxygen saturation (table). The slight increase in standard deviation observed at lower saturations may reflect the reduced size of the samples. There were 18 data points when S_EO_2 dif-

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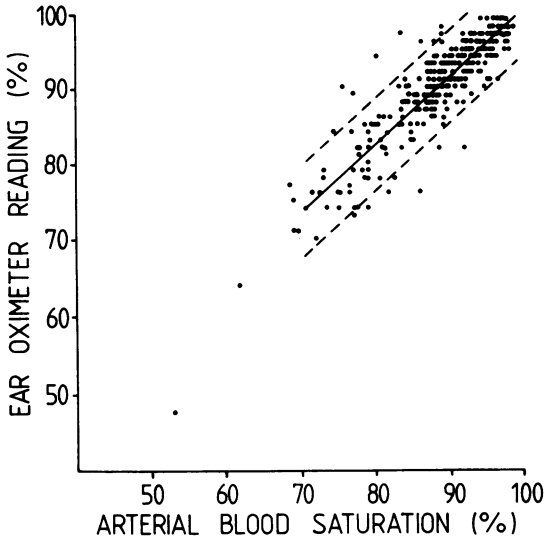

Biox IIA ear oximeter readings for oxygen saturation plotted against arterial blood saturation for 322 samples (regression line and 95% confidence limits of the data shown).

fered from Sao_2 by more than 6%. On three occasions the oximeter reading was too low, each of these data points lying between −6% and −10%. On 15 occasions the reading was too high, 11 of these data points lying between +6% and +10% and four between +12% and +14%. Two of the latter four values were in the Sao_2 range 89–80% and two in the range 79–70%.

The carboxyhaemoglobin concentrations were compared with the saturation difference (S_EO_2–Sao_2) in all patients but no correlation was found ($r = -0.18$, $p > 0.5$), neither did the grossly discrepant readings relate in any way to carboxyhaemoglobin concentration.

Discussion

This study shows that the Biox IIA ear oximeter is in the main accurate and useful in clinical practice, with 95% confidence limits of around ±6% in the normal operating range—compared with ±5% for the Hewlett Packard 47201A ear oximeter.[1] Further, the Biox readings reflect the actual arterial saturation irrespective of carboxyhaemoglobin concentration.

Increasing carboxyhaemoglobin has the dual effect of directly decreasing the amount of available haemoglobin and altering the shape of the haemoglobin dissociation curve.[5] The oxygen saturation measured by the ABL-2 Blood Gas Analyser assumes zero carboxyhaemoglobin and that displayed on the IL 282 CO-Oximeter expresses oxygen saturation as a percentage of total haemoglobin; therefore neither measurement indicates the actual saturation of the available haemoglobin in the patient's blood. For comparison with an ear oximeter reading it is thus necessary to calculate the actual saturation of each arterial blood sample. By this means the Biox was shown to reflect the actual saturation of available haemoglobin in arterial blood at all levels of carboxyhaemoglobin observed. A report that the Hewlett Packard ear oximeter was affected by carboxyhaemoglobin[1] probably results from the comparison of the oxygen saturation of the ear with the CO-Oximeter derived saturation (percentage of total haemoglobin).

While overall the accuracy of the ear oximeter readings was adequate for clinical purposes, we would consider discrepancies more than 10% (of which there were four) unacceptable. Since the actual saturation calculated from the arterial samples agreed well with the independent measurement of saturation corrected for carboxyhaemoglobin by the CO-Oximeter, these discrepancies must be attributed to the ear oximeter. The ear oximeters, however, were used in accordance with the strictest instructions of the manufacturer and only by staff who had been trained in their use. Further, measurements were taken only when the ear oximeter readings were stable and when no error lights were showing. None of the subjects' ears were grossly abnormal. The four widely discrepant values came from four different patients and none of these patients showed discrepancies on another occasion. Examination of the 14 lesser discrepancies of (±6–10%) showed that two patients each contributed two points and that one of these patients showed a

Comparison of ear oxygen saturation (S_EO_2) and actual arterial blood saturation (Sao_2) at different levels of arterial oxygen saturation

	Sao_2 range (%)				
	100–90	89–80	79–70	<70	Total range
Number of readings	158	123	35	6	322
Mean Sao_2 (%)	93.8	86.3	76.4	65.5	88.5
Mean (SD) difference (S_EO_2–Sao_2%)	+0.6 (2.2)	+2.3 (3.4)	+2.4 (4.4)	+2.4 (4.8)	+1.5 (3.0)

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difference of 10% in $S_{E}O_2$ between left and right ears. Seven of the other 12 patients with 6–10% errors were studied on another occasion, when the results obtained were satisfactory (<6% error). We suspect that these errors may result from inadequate ear perfusion undetected by this instrument.

There are now Biox III and Biox IV oximeters as well as the Biox IIA oximeter that was tested in this study. We are assured by the manufacturers that there are no appreciable differences in electronics between these oximeters and the Biox IIA, although the detection of inadequate perfusion is believed to have been improved (Ohmeda, personal communication). Thus these other oximeters would be expected to be at least as accurate as the Biox IIA and the improved detection of defects in perfusion might diminish the discrepant results.

Thus while the Biox IIA oximeter is easy to use, comfortable for the patient, and usually accurate, in routine practice occasional errors may occur that may be large enough to be misleading if a single reading from this instrument is used as the only measure of the patient's oxygenation.

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