Eur Respir J 1998; 11: 716–719
DOI: 10.1183/09031936.98.11030716
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European Respiratory Journal
ISSN 0903 - 1936

Accuracy of a pulse oximeter in the measurement of the oxyhaemoglobin saturation

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Accuracy of a pulse oximeter in the measurement of the oxyhaemoglobin saturation. F. Chiappini, L. Fuso, R. Pistelli. ©ERS Journals Ltd 1998.

ABSTRACT: The aim of the present study was to evaluate the accuracy, in comparison with a reference method, of the Nellcor N-20P pulse oximeter in the assessment of oxyhaemoglobin saturation (S_{a,O_2}).

S_{a,O_2} was monitored at rest by the Nellcor N-20P pulse oximeter in 100 subjects (82 males, mean age 68±12 yrs) consecutively enroled. At the same time, an arterial blood sample was collected for the measurement of S_{a,O_2}, carboxyhaemoglobin, and methaemoglobin by an IL-282 Co-oximeter.

A significant difference was found between S_{a,O_2} values measured with the two methods (t=11.78, p<0.05), but the two series of measurements were significantly correlated (r=0.97). Both the level and the limits of agreement between the two methods were satisfactory when the more appropriate Bland and Altman method was applied. Nevertheless, a lack of accuracy of the pulse oximeter was found, but only for S_{a,O_2} values <82% and >94%, as demonstrated by the Youden index.

In conclusion, these data show that Nellcor N-20P is sufficiently reliable for the assessment and monitoring of oxyhaemoglobin saturation. The lack of accuracy does not seem clinically relevant since it is appreciable only for values at the extremes of the oxyhaemoglobin saturation range.

Eur Respir J 1998; 11: 716–719.

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Keywords: Oxyhaemoglobin saturation
pulse oximeter
respiratory failure

Received: February 4 1997
Accepted after revision August 12 1997

The continuous monitoring of oxyhaemoglobin saturation (S_{a,O_2}) is nowadays widely employed in clinical management of subjects with respiratory failure and in critically ill or anaesthetized patients [1]. The assessment of S_{a,O_2} by using a spectrophotoelectric oximetric technique is the most useful method since it provides a noninvasive, continuous, and direct *in vivo* determination of S_{a,O_2} [2]. Pulse oximetry is based on two physical principles. Firstly, the absorption of light at two different wavelengths (one red = 660 nm and one infra-red = 940 nm) is different in oxygenated and in deoxygenated haemoglobin. Secondly, the absorption of light at two different wavelengths has a pulsatile component, resulting from the changing volume of arterial blood with each pulse beat, and this can be distinguished from nonpulsatile component due to venous, capillary, and tissue light absorption [3].

The pulse oximeter consists of a peripheral probe and a small microprocessor unit displaying a waveform, the oxygen saturation and the cardiac frequency. The oxygen saturation is calculated by comparing the proportion of light absorbed at each of two different wavelengths with a stored value. The method presents some limitations [4, 5]: of particular importance is the false reassurance of a "normal" S_{a,O_2} in a sedated patient receiving high concentrations of supplemental oxygen [6]. However, it is a very useful method for detecting the presence of hypoxaemia inferred from a reduced S_{a,O_2} value.

Several pulse oximeters are now available; the agreement among them in S_{a,O_2} measurement and the accuracy of these instruments in comparison with a reference method are of crucial importance in order to obtain reliable S_{a,O_2} values and, thus, reliable clinical information [7–11].

The aim of the present study was to assess the accuracy of a new pulse oximeter, Nellcor N-20P (Nellcor Incorporated Hayward, CA, USA). To this end, S_{a,O_2} values derived noninvasively from this instrument (S_{p,O_2}) were compared with saturation values measured in arterial blood sample by a IL-282 Co-oximeter (Instrumentation Laboratory, Lexington, USA), considered as reference method of measurement.

Nellcor N-20P was chosen because it is a very cheap instrument, widely diffused in southern Europe. Moreover, the mainboard of this oximeter is included in many instruments used for the telemonitoring (*i.e.* long distance data transmission *via* modem and telephone connection) of patients in domiciliary long-term oxygen therapy.

Materials and methods

One hundred subjects (82 males, mean age 68±12 yrs), were recruited among all the patients who underwent an arterial blood gas analysis in our laboratory for a respiratory diagnostic screening in a 1 month period; 19 patients were receiving oxygen therapy at the time of the study.

Table 1. – Arterial gas data, values of functional oxygen saturation (Sf,O_2), total haemoglobin and other haemoglobins derived from IL-282 Co-oximeter, of the patients subgrouped according to the inhaled oxygen fraction

	FI,O_2 %					
	21	24	28	31	35	100
Patients n	82	5	6	4	2	2
Pa,O_2 mmHg	63.0±15.2	69.8±17.4	58.4±9.1	59.8±6.5	78.1±12.3	82.7±14.0
Pa,CO_2 mmHg	46.2±9.8	49.4±9.3	58.7±18.0	69.3±14.0	35.4±2.5	45.2±18.3
pH	7.4±0.03	7.4±0.03	7.37±0.04	7.37±0.04	7.43±0.04	7.40±0.05
Sf,O_2 %	91.5±6.6	94.5±5.7	89.9±4.5	91.4±2.3	98.2±1.5	96.8±0.8
Total Hb %	14.6±2.1	14.6±2.6	13.8±2.5	12.7±2.0	12.9±5.9	18.4±11.5
COHb %	3.4±1.2	3.4±0.5	3.1±0.7	2.7±0.2	4.2±1.3	3.0±0.1
MetHb %	0.38±0.38	0.80±0.20	0.47±0.37	0.28±0.36	0.2±0.10	0.1±0.05

Values are mean±SD. FI,O_2: inhaled oxygen fraction; Pa,O_2: arterial oxygen tension; Pa,CO_2: arterial carbon dioxide tension; Hb: haemoglobin; COHb: carboxyhaemoglobin; MetHb: methaemoglobin.

The arterial blood sample was collected according to the criteria of the British Thoracic Society [12]. Briefly, each sample was collected anaerobically in heparinized syringes, was mixed within the syringe for 2 min, and then immediately analysed, without any contact with room air, by a Radiometer ABL-330 (Radiometer, Copenhagen, Denmark) computerized system for the determination of arterial oxygen and carbon dioxide tension (Pa,O_2 and Pa,CO_2, respectively), and pH, and by a IL-282 Co-oximeter for the measurement of Sa,O_2 and the percentage of carboxyhaemoglobin, and methaemoglobin. The instruments were calibrated daily with quality-control vials, according to the instruction manual. During the arterial blood sample collection, Sp,O_2 was measured with the pulse oximeter Nellcor N-20P equipped with a reusable finger probe, placed on the second finger of the subject's dominant hand. This saturation can be regarded as a functional saturation related to the presence of reduced haemoglobin which the pulse oximeter is able to identify. Thus, in order to make comparable the measurement performed with the pulse oximeter and with the Co-oximeter, a functional oxygen saturation (Sf,O_2) was derived also from the fractional saturation measured with the IL-282 Co-oximeter using the following formula:

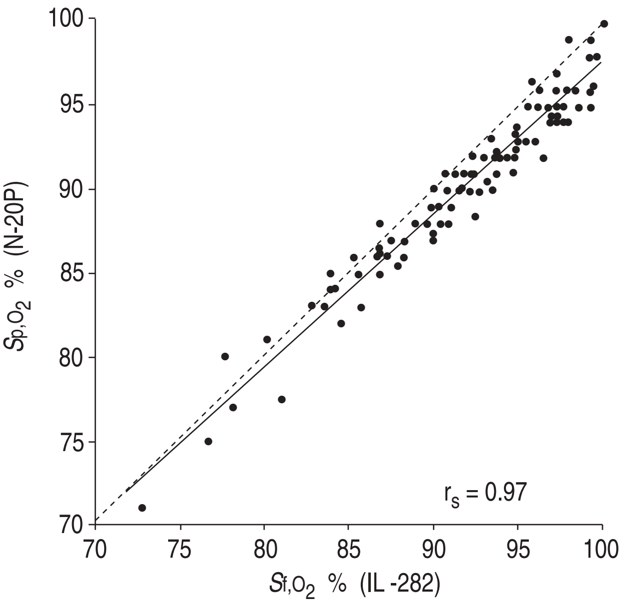

Fig. 1. – Oxygen saturation measured with pulse oximeter (Sp,O_2) (Nellcor N-20P) plotted against functional oxygen saturation (Sf,O_2) measured with Co-oximeter IL-282. ——: regression line; ------: identity line; r_s: correlation coefficient.

$$S\text{f},O_2 = \text{fractional saturation} / (100 - (\text{carboxyhaemoglobin} + \text{methaemoglobin})) \cdot 100$$

The statistical analysis was performed using the paired t-test for a comparison between means; the relationship between variables was evaluated by a linear regression analysis; the agreement between the two methods of measurement was assessed according to the method proposed by Bland and Altman [13]; the Youden index (sensitivity + specificity-1) [14] was finally calculated every three percentage units of saturation from 79 to 97% of Sf,O_2. The Youden index was used as a global index of performance and accuracy; it ranges from 1 to -1 and the higher is its values, the higher is the accuracy of the test.

Results

The arterial gas data of the patients subgrouped according to the inhaled oxygen fraction, in addition to the Sf,O_2 values, and the values of total haemoglobin and of the other haemoglobins obtained from the IL-282 Co-oximeter, expressed as mean±SD, are reported in table 1.

The IL-282 Co-oximeter provided higher values of Sa,O_2 in comparison with Nellcor N-20P with a statistically significant difference when using the paired t-test. (Sf,O_2 value = 92.14±5.79 *vs* Sp,O_2 = 90.58±5.45 ($t = 11.78$, $p<0.05$).

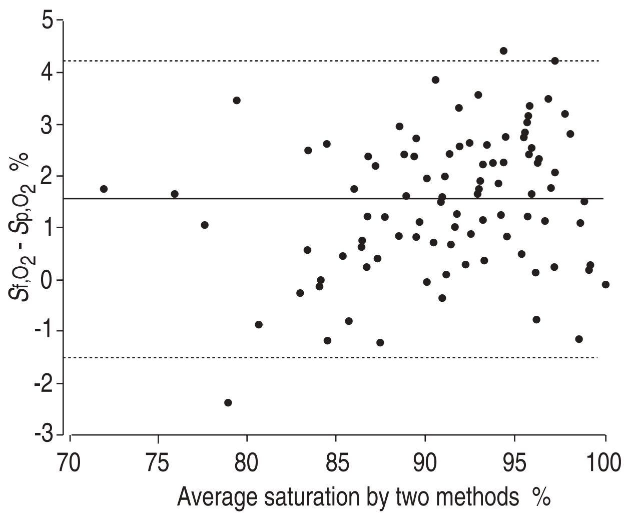

Fig. 2. – The agreement between the two methods. Difference in saturation (Sf,O_2 - Sp,O_2) plotted against average saturation by two methods. : mean; ------- : mean plus or minus 2SD; Sf,O_2: functional oxygen saturation; Sp,O_2: oxygen saturation measured by pulse oximetry.

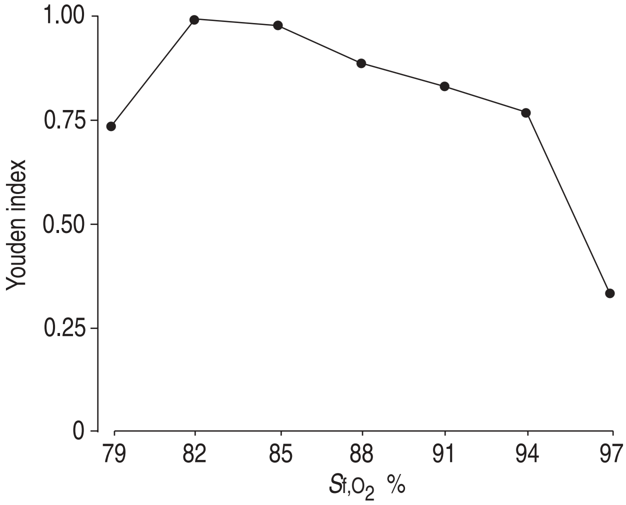

Fig. 3. – The Youden index calculated every three percentage units of functional oxygen saturation (Sf,O_2) from 79 to 97%.

In figure 1, Sp,O_2 values measured with Nellcor N-20P are plotted against Sf,O_2 values measured with IL-282. The correlation was highly significant (r=0.97).

The agreement between the two methods is shown graphically in figure 2. The difference between the two methods was 1.56% with Sf,O_2 values higher than Sp,O_2 values, and the limits of agreement (mean±2SD) [13] ranged from -1.08 to 4.20.

The Youden index calculated for saturation values ranging 79–97% is reported in figure 3. The discrepancies between the two methods were evident only for saturation values <82% and >94%.

Discussion

Pulse oximetry is an important part of the monitoring of patients under general anaesthesia, in the recovery room and in intensive care. Moreover, when it is not possible to obtain arterial gas data, this method can be useful as a screening diagnostic procedure in patients with lung diseases in whom the clinical conditions do not always reflect the actual level of the Sa,O_2. The accuracy of measurement must be a necessary characteristic of the instruments used in the diagnostic procedure.

The Co-oximeter is generally considered as the reference method in order to assess the accuracy of the pulse oximeters [15]. The Co-oximeter employs a spectrophotometric method at four different wavelengths (535.0, 585.2, 594.5, and 626.6 nm) to detect four fractions of haemoglobin: oxyhaemoglobin, deoxygenated haemoglobin, carboxyhaemoglobin and methaemoglobin. The pulse oximeter employs only two wavelengths to discriminate between reduced and not reduced haemoglobin. The reduced haemoglobin is functionally apt to transport oxygen but it can also bind carbon monoxide or contain ferric ion as in the methaemoglobin. It follows that the pulse oximeter is not able to detect the presence of carboxyhaemoglobin and methaemoglobin; moreover, it is useful to obtain the values of reduced and not reduced haemoglobin also from the Co-oximeter, using the above-reported formula, in order to homogeneously compare the two methods of measurement.

Several studies are reported in literature about the validation of pulse oximeters and about the concordance of measurements obtained by different instruments [7, 8, 10]. However, the t-test and the simple regression analysis used in these studies are not able to assess the agreement between two methods of measurement adequately, as is possible with the BLAND and ALTMAN [13] method applied in our study.

In this study, Nellcor N-20P was tested because its mainboard is the same as that of several instruments used for the telemonitoring of Sa,O_2 measurements. Thus, the adequacy of a long-term oxygen therapy depends, at least in part, on the accuracy of the mainboard included in this pulse oximeter.

Our data indicate that the traditional method of analysis provided conflicting results. A significant difference was found between the saturation values measured with the Co-oximeter and with the pulse oximeter. However, a highly significant correlation coefficient was found between the values derived from the two methods (fig. 1). It is known that, according to the method proposed by BLAND and ALTMAN [13], a plot of the difference between methods against their mean may be more informative and allows us to calculate the limits of agreement between the two methods. According to BLAND and ALTMAN [13], a tendency of the pulse oximeter to underestimate the sat-uration values in comparison with the Co-oximeter was evident from our data (fig. 2). However, the level of agreement between the two methods seems satisfactory: the mean difference between the two methods was 1.56%, similar to that indicated by the manufacturer who reports, for Nellcor N-20P, a standard error in measurement of 1.5%. Moreover, the limits of agreement derived from our data were only slightly wider than those obtained by TYTLER and SEELEY [16] who analysed the accuracy of the Nellcor 101 pulse oximeter. These limits were considered small by BLAND and ALTMAN [13] who reported the data of TYTLER and SEELEY [16] as an example of good agreement bet-ween two methods. Nevertheless, an error in accuracy, even if statistically not relevant, could be clinically important, determining potentially dangerous consequences and a misclassification of the patients studied if it concerned some points of the dissociation curve of oxyhaemoglobin. For this reason, we examined the accuracy of the pulse oximeter separately for the whole range of saturation values. Our results show that the difference between the two methods was maximal only for Sf,O_2 values <82% and >94% characterized by a low Youden index (fig. 3). In the former case, the severe desaturation indicates the need for a further diagnostic evaluation with the collection of an arterial blood sample for the arterial gas analysis. In the latter case, the risk of a misclassification does not influence the clinical management since it concerns high saturation values. Thus, the clinical consequence of the poor accuracy of the pulse oximeter in comparison with the Co-oximeter does not seem clinically relevant since it concerned only the highest and lowest values of the Sf,O_2 distribution.

In conclusion, our results show that the pulse oximeter Nellcor N-20P is a useful and a sufficiently reliable method for the diagnostic screening and monitoring of patients affected by pulmonary diseases. The lack of accuracy in comparison with a standard reference method is appreciable only for values at the extremes of the oxyhaemoglobin saturation range.

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