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

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The continuous monitoring of oxyhaemoglobin saturation (SaO₂) is nowadays widely employed in clinical management of subjects with respiratory failure and in critically ill or anaesthetized patients [1]. The assessment of SaO₂ by using a spectrophotoelectric oximetric technique is the most useful method since it provides a noninvasive, continuous, and direct in vivo determination of SaO₂ [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” SaO₂ 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 SaO₂ value.

Several pulse oximeters are now available; the agreement among them in SaO₂ measurement and the accuracy of these instruments in comparison with a reference method are of crucial importance in order to obtain reliable SaO₂ 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), 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.
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 (P_{a,O_2} and P_{a,CO_2}, respectively), and pH, and by a IL-282 Co-oximeter for the measurement of S_a,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, SpO_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 (S_{f,O_2}) was derived also from the fractional oxygen saturation (S_{f,O_2}) plotted against functional oxygen saturation (S_{f,O_2}) measured with Co-oximeter IL-282.

\[ S_{f,O_2} = \frac{S_{O_2}}{100} \times \frac{100}{(100 - (\text{carboxyhaemoglobin} + \text{methaemoglobin}))} \]

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 \( S_{f,O_2} \). 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 \( S_{f,O_2} \) 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 S_a,O_2 in comparison with Nellcor N-20P with a statistically significant difference when using the paired t-test. (S_{a,O_2} value = 92.14±5.79 vs S_{a,O_2} = 90.58±5.45 (t = 11.78, p<0.05).

<table>
<thead>
<tr>
<th>Patients n</th>
<th>21</th>
<th>24</th>
<th>28</th>
<th>31</th>
<th>35</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>P_{a,O_2} mmHg</td>
<td>63.0±15.2</td>
<td>69.8±17.4</td>
<td>58.4±9.1</td>
<td>59.8±6.5</td>
<td>78.1±12.3</td>
<td>82.7±14.0</td>
</tr>
<tr>
<td>P_{a,CO_2} mmHg</td>
<td>46.2±9.8</td>
<td>49.4±9.3</td>
<td>58.7±13.0</td>
<td>69.2±14.0</td>
<td>35.4±2.5</td>
<td>45.2±18.3</td>
</tr>
<tr>
<td>pH</td>
<td>7.4±0.03</td>
<td>7.4±0.03</td>
<td>7.37±0.04</td>
<td>7.37±0.04</td>
<td>7.43±0.04</td>
<td>7.40±0.05</td>
</tr>
<tr>
<td>S_{f,O_2} %</td>
<td>91.5±6.6</td>
<td>94.5±5.7</td>
<td>89.9±4.5</td>
<td>91.4±2.3</td>
<td>98.2±1.5</td>
<td>96.8±0.8</td>
</tr>
<tr>
<td>Total Hb %</td>
<td>14.6±2.1</td>
<td>14.6±2.6</td>
<td>13.8±2.5</td>
<td>12.7±2.0</td>
<td>12.9±5.9</td>
<td>18.4±11.5</td>
</tr>
<tr>
<td>COHb %</td>
<td>3.4±1.2</td>
<td>3.4±0.5</td>
<td>3.1±0.7</td>
<td>2.7±0.2</td>
<td>4.2±1.3</td>
<td>3.0±0.1</td>
</tr>
<tr>
<td>MetHb %</td>
<td>0.38±0.38</td>
<td>0.80±0.20</td>
<td>0.47±0.37</td>
<td>0.28±0.36</td>
<td>0.2±0.10</td>
<td>0.1±0.05</td>
</tr>
</tbody>
</table>

Values are mean±SD, P_{f,O_2}: inhaled oxygen fraction; P_{a,O_2}: arterial oxygen tension; P_{a,CO_2}: arterial carbon dioxide tension; Hb: haemoglobin; COHb: carboxyhaemoglobin; MetHb: methaemoglobin.

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Fig. 1. – Oxygen saturation measured with pulse oximeter (SpO_2) (Nellcor N-20P) plotted against functional oxygen saturation (S_{f,O_2}) measured with Co-oximeter IL-282.

Fig. 2. – The agreement between the two methods. Difference in saturation (S_{a,O_2} - SpO_2) plotted against average saturation by two methods.
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 SaO₂ 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 saturation 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 Tyler and Seely [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 Tyler and Seely [16] as an example of good agreement between 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 SaO₂ 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 SaO₂ 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 appre-
ciable only for values at the extremes of the oxyhaemoglobin saturation range.

References