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Original Article

Internal Medicine Section

Concordance among Measurements Obtained by Three Pulse Oximeters Currently Used by Health Professionals

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ABSTRACT

Introduction: Oxygen saturation is considered as the 5th vital sign. Presently, there exist fixed and wireless pulse oximeters, being the latter most widely used in the last years. Some of them have no possibility of calibration. This situation leads the health staff to adopt therapeutic attitudes which can be wrong. Therefore, it is extremely important to know if these wireless oximeters show a right concordance as regards measurements, since it is of great interest in daily clinical practice.

Objective: To evaluate concordance among measurements obtained by three different pulse oximeters currently used by health professionals.

Materials and Methods: This is an observational, descriptive and cross-sectional study related to the concordance of the results obtained in measurements collected by three different pulse oximeters (one monitor and two wireless oximeters) which are available and in use in this hospital unit. The sample size calculation was performed for a concordance above 0.81 and an estimation error which did not exceed 0.20. The intraclass correlation index (ICI) was used to establish the concordance whereas the Landis-Koch criteria were used to interpret the results. Systematic errors were analyzed using the Bland-Altman plot.

Results: The overall concordance among the three pulse oximeters analyzed resulted in 0.88, a value considered as "good" according to the Landis-Koch criteria.

Conclusion: The results obtained show that in daily clinical practice both wireless pulse oximeters analyzed can be used with a certain reliability, taking into account the limitations of this research.

Keywords: Gases, Monitoring, Oximetry, Pulse oximeter

INTRODUCTION

Pulse oximetry is a technique which determines oxygen saturation in arterial blood, measuring light absorbed by haemoglobin in a pulse flow [1]. It is based on [2] the principles of plethysmography and spectrophotometry. At present, it can be considered as the "fifth vital sign" [3,4] since it not only values respiratory function but also the presence, amplitude and frequency of the peripheral pulse. In order to determine blood oxygen percentage in a peripheral and non-invasive way, instruments such as pulse oximeters or saturometers can be used. These devices let us measure blood oxygen percentage. Generally, these are finger clipped devices adapted to the human digit and include a light detector [3,5] and a light source with two waves, a red light of wavelength 660 nm and an infrared light of wavelength 940, which are respectively characteristic of oxyhaemoglobin and reduced haemoglobin. Most of the light is absorbed by the connective tissue, skin, bone and venous blood in a constant amount, producing a small increase of this absorption in the arterial blood with each heartbeat. This means that it is necessary the presence of the arterial pulse to let the device recognize any sign.

Oxyhaemoglobin percentage is measured by comparing the light absorbed during the pulse wave and the basal absorption. Net absorption is only measured during a pulse wave, minimizing the influence of tissues, veins and capillaries in the result [6].

When the oximetry is going to be performed several aspects must be taken into account: the pulse oximeter must be placed in the finger and information such as oxygen saturation, cardiac frequency and pulse curve [3] must be displayed on the screen.

Some factors [2] appear to influence oxygen saturation measurement such as severe anaemia, patient's movements, intense light, peripheral vascular problems, venous pulse and interferences with other devices.

Most manufacturers and models of wireless pulse oximeters in the present market lead us to consider the reliability and accuracy of these devices in daily clinical practice. Nevertheless, there are other factors associated to individuals, to observers and to measuring devices [7,8] that can affect measurements [7]. Because of this, aspects such as repeatability, intraobserver and interobserver concordance and concordance among methods for measuring must be taken into account.

Peripheral pulse oximetry, performed on a daily basis by the nursing staff in the hospital environment, aims at detecting low oxygen content in blood. Until recently, hospital units only had monitors with saturation measuring devices examined and calibrated [9] by the electromedicine unit. However, in the last years wireless saturometers, which do not offer any possiblility of calibration, have been increasingly used by hospital services.

In the Trauma and Orthopaedic ward, where this research has been performed, there are monitors supplied by Nelcor® Institution (several models) which allow a fixed saturation monitoring. At the same time, there are two models of portable wireless pulse oximeters (Contec®: CMS-50A [10] and CMS-50B [10] models). Calibration functions of Nelcor® monitor N5600 [11] are checked annually by the Electromedicine Service whereas both portable wireless oximeters, which have been used for one year by the nursing staff, have not been inspected and calibrated since they were manufactured.

The revision process of nursing records by the health staff, as regards those measurements obtained, leads us to make a diagnostic judgement and to adopt concrete therapeutic attitudes that can be wrong if the device does not show a right reading of the data. Therefore, it is extremely important to know if the devices which are most used by nurses in order to measure PaO_2 in our care unit show a right concordance in the measurements they record since it is of a great interest [12,13] in daily clinical practice.

GENERAL OBJECTIVE

To evaluate the concordance among measurements obtained by three different pulse oximeters currently used by health professionals in the trauma and orthopaedic ward unit in Hospital Insular de Gran Canaria.

MATERIALS AND METHODS

This is an observational, descriptive and cross-sectional study related to the concordance of the results obtained in measurements collected by three different pulse oximeters (one monitor and two wireless oximeters) which are available and in use in this hospital unit. The sample of patients was selected from the hospital unit of Trauma and Orthopaedic Surgery (TOS) in Hospital Insular de Gran Canaria in the last trimester in 2012. The main characteristics of patients selected were the following ones: saturation > 90% and average age > 60, with a prevalence of pathologies such as femur fractures, gonarthrosis and coxathrosis.

The sample size was determined taking into account a high concordance among the three devices (concordance above 0,81) and an estimation error below 0,20. Therefore, with these conditions it was necessary to select a sample of at least 33 patients.

Exclusion criteria for participation in the study were the following ones: patients suffering from dementia, Alzheimer, transient disorientation and/or impossibility of communication, who presented fractures or amputation of both upper limbs, haemoglobin <8gl/dl and febrile state in process (T > 37).

Instruments: *Monitor Nelcor® 5600* [11] (LED visualization, red light of wavelength 660nm and infrared light of wavelength 940nm, it can measure the SpO_2 level, cardiac frequency, electrocardiogram, respiratory rate, blood pressure, temperature, plestimographic curve, range of measurement SpO_2 1-100%, precision %SpO2 ± 1 SD%), *portable wireless pulse oximeter Contec® CMS-50A*[10] (LED visualization, red light of wavelength 660nm and infrared light of wavelength 880nm, it can measure the SpO_2 level, cardiac frequency and plestimographic curve, range of measurement SpO_2 0-100%, resolution 1% for SpO_2, accuracy SpO_2 70-100% ± 2%, SpO2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4% - SpO_2 error is ±4%), *portable wireless pulse oximeter Contec® CMS-50B*[10] (LED visualization, it can measure the SpO_2 level and cardiac frequency, red light of wavelength 660nm and infrared light of wavelength 880nm. range of measurement SpO_2 35-99%, accuracy SpO_2 70-99% ± 2, SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%). The monitor has been calibrated by the electromedicine unit. Both wireless oximeters have been used by the health staff for one year without being calibrated.

A template was created for this study to collect data. The first section includes sociodemographic data: age, sex, and present pathologies, whereas the second section contains those measurements obtained by the three peripheral oximeters currently used in TOS Unit: Nelcor® N5600 [11] monitor to measure fixed peripheral oximetry and two portable wireless oximeters (Contec® CMS-50A [10] and CMS-50B [10]). The monitor in the unit is inspected annually by the electromedicine service whereas the portable wireless oximeters, which have been used for one year by the nursing staff, have not been examined and calibrated since they were manufactured.

The main variable which is the object of our study is related to the different types of devices, whereas independent variables refer to the three models of oximeters. The dependent variables make reference to the values expressed in percentage that these show.

The process prior to the measurement is described as follows:

- To check the afebrile situation
- To identify haemoglobin higher than 8gr/dl in the last blood test
- To evaluate the absence of dementia, disorientation and/or communication disorders
- To explain the objective of the study and the technical procedure, asking for patient consent and collaboration.

Measurements using the three different pulse oximeters were always performed by the same nurse. Pulse oximeters were always placed on the same finger of the patient. Saturation was measured after 30 seconds with the measuring device placed on the fingertip, being the process repeated three times with the three saturometers. All measurements were performed in the same place of the room, to keep the same room light intensity, asking the patient to be immobile during the process.

The access to patients' medical records has been obtained after asking permission in the Teaching and Investigation Unit in Materno-Insular University Hospital Complex in Gran Canaria with authorization date April 1st 2012. Confidentiality of those medical data obtained has been maintained.

Analysis strategy: The statistics used were median, standard deviation and range. The study of concordance among the three saturometers was performed using the intraclass correlation index (ICI) [8,13,14] and the results were interpreted using the Landis-Koch criteria. These criteria consider concordance as "very good" ICI >0.91, "good" from 0.71 to 0.90, "moderate" 0.51-0.70, "fair" 0.31—0.50 and "poor" below 0.31.

The detection of possible systematic errors was explored by means of Bland-Altman diagrams [15].

The statistical package used was SPSS 17.0 and R software, which have permission to be used.

RESULTS

Seventy eight patients were selected, 51.3% female patients (40) and 48.7% male patients (38%) with an average age of 68.72, a standard deviation of 18.165 and a range of 21-98 years old. 5.1% (4) were patients who require oxygen therapy during measurement. 94.9% (74) did not require this therapy.

51.3% (40) measurements were performed in upper right limbs whereas 48.7% (38) in upper left limbs.

The concomitance of pathologies, which could influence blood oxygen measurement, was identified in the sample and it was found that 44.9% of patients (35) suffered from hypertension, 20.5 % (16) from Diabetes Mellitus, 26.9% (21) from cardiovascular disorders and 15.4% (12) from respiratory disorders.

[Table/Fig-1] shows the descriptive statistics obtained by the three pulse oximeters and [Table/Fig-2] shows the average measure intraclass correlation indexes (ICI 95%).

With the aim of verifying the possible presence of systematic, constant and proportional errors a graphic study was carried out using dispersion diagrams [Table/Fig-1-5] where there is a clear evidence of the absence of systematic errors.

As regards the concordance among those measurements obtained by the three pulse oximeters which are at present clinically used, and after applying the Landis-Koch criteria in their interpretation, it can be stated that they have been achieved as it is shown in the results section [Table/Fig-1,2].

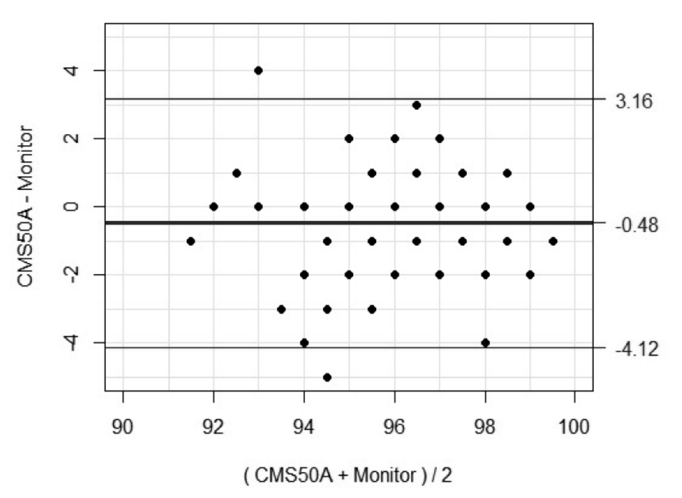
The average measure intraclass correlation index was 0.88. This shows a concordance which is considered as "good" (between 0.71 and 0.90) [15], next to the concordance range considered as "very good" (ICI $\geq$ 0.91) [16].

	N	Minimum	Minimum	Media	SD
NELCOR	78	92.0	100.0	96.481	1.8612
CMS50A	78	91.5	99.0	96.026	1.8759
CMS50D	78	92.0	98.5	95.609	1.8120
Valid N (listwise)	78				

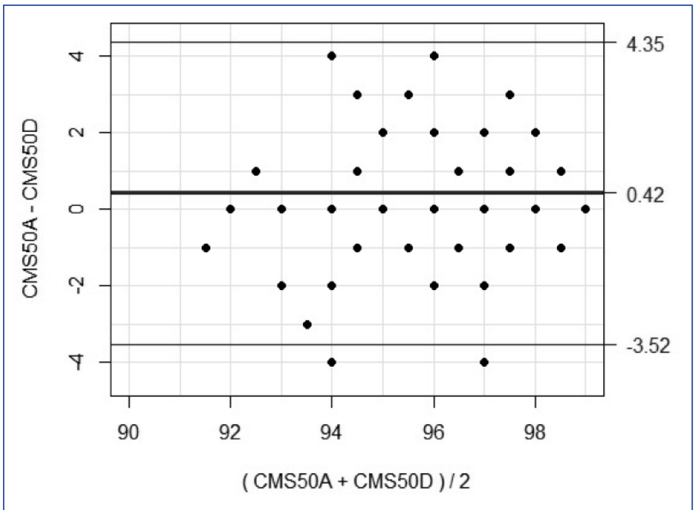
[Table/Fig-1]: Descrptive statistics of the three pulse oximeters

	N	95% Confidence interval		F test with true value 0			
	Intraclass correlation	Lower limit	Upper limit	Valor	df1	df2	Sig
Simple measures	.713	.616	.795	8.470	77	154	.000
Average measures	.882	.828	.921	8.470	77	154	.000

[Table/Fig-2]: Intraclass correlation coefficient (ICC). Concordance among oximeters



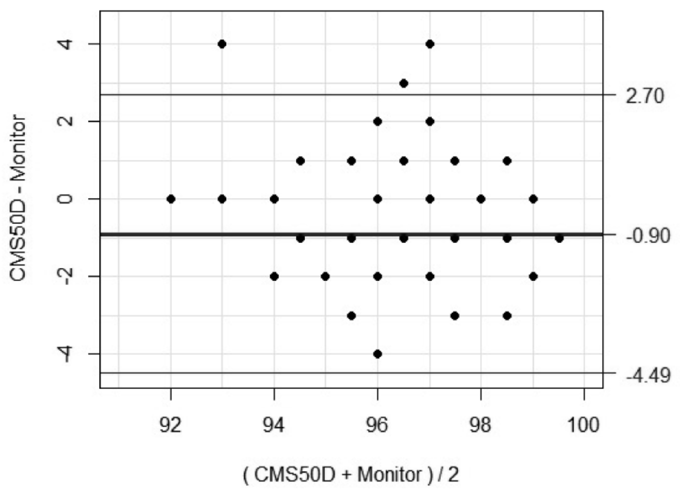
[Table/Fig-3]: Dispersion Diagram (Between Monitor And Cms50a Wireless Oximeter)



[Table/Fig-4]: Dispersion Diagram (Between Cms50a And Cms50d Wireless Oximeters)

DISCUSSION

The overall concordance among the three pulse oximeters analyzed is considered as "good" according to the Landis-Koch criteria [16]. These results lead us to conclude that in daily clinical practice, health professionals (doctors and nurses) in hospital and emergency services can use both wireless pulse oximeters analyzed with reliability as regards their results, taking into account the limitations of the present study due to the absence of "gold standard", arterial gasometry.



[Table/Fig-5]: Dispersion Diagram (Between Monitor And Cms50d Wireless Oximeter)

Authors [17,18] state of existence a variety of situations and objects that may affect the correct reading of the oximeter. which in this specific study have not been taken into account because the objective of this research was to study the concordances between the devices provided by the health institutions and those acquired by health professionals, being all measurements performed in the same environmental conditions.

On the other hand, from the point of view of electromedicine [18], it is relevant to emphasize the importance of sensors in this type of devices, their calibration and measurements accuracy because many mistakes have been made due to the different wavelengths in LED and the risks which these mistakes can produce in patients, especially in conditions with low levels of oxygen saturation in arterial blood. Therefore, more control and supervision is required from the manufacturers during the production of the pulse oximetry sensor or the selection of its suppliers.

As it was stated above, there exist clinical scenarios where oximetry loses its utility [18], as in the case of CO_2 intoxications and laryngitis. Therefore, the health staff who make use of this instrumentation need to be aware of this situation.

At present, new researches are being developed [5]. These try to incorporate new technologies in these wireless diagnostic devices, adding new parameters such as hemoglobin, being the hemoglobinometer the measuring device. These new technologies are being increasingly incorporated in hospital settings (overall in hospital and emergency services) due to their low cost if it is compared to the cost of maintenance of a standard device in the above mentioned services and the cost which is added of the finger sensor used individually. These sensors must be changed frequently with each patient if we want to get a proper functioning. There is also a need of change when the monitor is being shared by other patient. These situations imply an increase in cost for the health institution. The introduction of new functions in pulse oximeters implies progress as regards its ease of use. Nevertheless, it leads us to analyze if the increase in measuring parameters in a physical device which has not been inspected and calibrated, will continue being safe showing those measurements and records performed by health professionals with reliability, and if they are efficient to perform a right diagnostic and medical treatment in the different clinical situations in which they are going to be used.

Another aspect to bear in mind is related to the safety guarantee of those data provided by the different pulse oximeters. This aspect has to do with the right interpretation of the results as regards those measurements obtained. This interpretation does not only depend on the device reliability, but also on the training of those who use it. A recently published study [19] shows that 80% of those people who use these devices are able to interpret what the oximeter measures, 40-45% know how they function and only 10-15% are able to interpret the haemoglobin dissociation curve. This fact makes us think that it is necessary to open new lines of research which let us identify the level of knowledge and training of health professionals when using these measuring devices.

CONCLUSION

To sum up, it is extremely important to guarantee the efficacy and reliability of those measuring devices which are being daily used in investigation and clinical practice and to enhance the need for continuous professional development of those who use these measuring devices to make clinical decisions, with the aim of satisfying key aspects related to patient security.

Taking into account the above-mentioned points, it would be advisable to plan the health professionals' interventions, if these devices are regularly inspected and calibrated according to the indications given by each brand name and model number.

Due to the existence of previous studies in scenarios where oximetry loses its utility and where there is a great variety of situations and artifacts which can affect the correct reading of the oximeter, this investigation group is presently researching in this field considering the different clinical situations in a third level hospital and in different periods of the life cycle of non-calibrated wireless oximeters with the aim of finding new correlations.

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