Evaluation of accuracy of portable fingertip pulse oximeter, as compared to that of a hospital oximeter with digital sensor

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ABSTRACT

Context: The pulse oximeter is a device that noninvasively provides continuous information about the peripheral oxygen saturation (SpO2) rate. This device is utilized in the detection of hypoxemia, due to its able to sense changes in hemoglobin oxygen saturation.
Aims: The objective of this study was to verify the accuracy of the Choice® Medical MD300C3 Fingertip Pulse Oximeter, as compared to that of a hospital oximeter coupled with a Dräger® Infinity Delta monitor, with the purpose of using this first methodology in dental procedures to monitor the peripheral oxygen saturation (SpO2) of patients submitted to dental treatments.
Materials and Methods: Fifty-five adult patients, both genders, were selected in the Santa Casa Hospital of Maringa, Brazil. The volunteers did not present cardiac problems, prosthetic cardiac valves, pacemakers, or pulmonary diseases, and were not pregnant or children. Each patient received a portable fingertip pulse oximeter (PPO) on the middle finger of the left hand and the hospital oximeter (control device) on the forefinger of the same hand. A total of six measurements were developed. The Pearson correlation coefficient and the Bland and Altman method was used to calculate the statistical analysis.
Results: No statistically significant difference was found between the measurements taken by the utilized devices. The average of comparative analysis presented by the devices was 0.2337 ± 0.4355 (mean ± SD), suggesting a strong correlation between the obtained results.
Conclusion: According to the methodology of the research, the PPO has similar accuracy to the conventional hospital oximeter with digital sensor. The PPO can be used in dental treatments.

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The pulse oximeter is a device that noninvasively provides continuous information about the peripheral oxygen saturation (SpO2) rate. This device is utilized in the detection of hypoxemia, due to its ability to sense changes in hemoglobin oxygen saturation. Hypoxemia is a clinical picture that can occur at any moment, requiring special care with ventilation within both hospital or private practice environments.[1,2]

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Furthermore, SpO2 oximeters also provide information about cardiac frequency and pulse rate. The measurements of these data are developed by means of sensors that can be installed in several parts of the body, but preferably in places where blood flow is more intense, such as the forehead just above the orbital area, cheeks, fingers, feet, and neck.[3,4]

At the present time, the most frequently used sensors are those designed to be placed on body extremities. Their efficacy has been well reported in literature.[4] In digital oximetry, two diodes emit light in red and infrared wavelengths that penetrate through tissues. The pulse oximeter provides readings of blood oxygen saturation levels, evaluating the absorption behavior of oxyhemoglobin and deoxyhemoglobin with respect to wavelengths of red and infrared light. The device has a receptacle to accommodate the distal phalanx of the finger that emits a light composed of two light emitting diode type photoemitters, which is sensed by a photodetector. One light emitting diode emits red light (660 nm), and the other emits infrared light (940 nm).

The calculation of SpO2 is determined by the ratio of the transmitted red light and the infrared light reflected by the site on which the sensor was placed.[5,6]

The applicability of oximeters is not restricted to hospital environments. Although pulse oximeters are not commonly found in dental offices, they are potentially valuable not only for the treatment, but also for the monitoring of vital sign changes in patients, especially those with cardiopulmonary problems.

Fear of dental treatment is common, and the associated anxiety is frequently responsible for a condition of stress, which initiates urgencies and medical emergencies that present an incidence of about 75% in dental offices.[7] Dentists should be prepared to intervene in these episodes, recognizing and diagnosing them as soon as they occur or are about to occur, decreasing the chance of irreversible damages in their patients' life. According to Dionne *et al.*,[8] the stress prior to anesthetic interventions or dental procedures drastically increases the amount of anesthesia necessary for the procedures, achieving an excess of 2% for routine procedures such as prophylaxis, 47% for dental extractions, 55% for endodontic treatments, and 68% for periodontal surgeries.

In dentistry, the monitoring procedure is more effective than merely conducting visual inspection or follow-up of patients' vital signs. The use of conventional oximetry devices, such as those available in hospital environments, has actually stopped being financially viable for dental offices. An alternative is the utilization of portable digital pulse oximeters (PPO). To this end, this study was developed to verify the accuracy between two types of oximeters and compare the values indicated by a PPO to those obtained using a table oximeter with digital sensor, a device commonly found in hospitals.

MATERIALS AND METHODS

This study was approved by the Human Ethics Committee (Protocol 0238.0.093.000-11). The study was conducted at Santa Casa Hospital of Maringá, Paraná, Brazil. The protocol sequence and the importance of its development were explained to the patients beforehand. All participants read and signed informed consent statements prior to the initiation of the study. Fifty-eight patients, both genders, with ages ranging from 18 to 86 years and who would be submitted to oral and medical surgery, were selected. Patients with cardiac problems, prosthetic cardiac valves or pacemakers, pulmonary diseases or any limitation that could hinder the adequate placement of the device were all excluded, as well as children and pregnant women.

The Pulse Oximeter Fingertip® MD300C3 (Beijing Choice Electronic Technology Co., Beijing, China) was established as the tester oximeter. The hospital oximeter was coupled with a Dräger® Infinity Delta (Drägerwerk AG – Lübeck – Germany) monitor, which was used as a control. The patients had their arms immobilized according to hospital protocol in order to avoid movements during the surgical procedure and prevent any damage to monitoring of vital signs. The sensor of the tester oximeter was positioned on the middle finger of the hand opposite that is used for the placement of the inflatable cuff of the sphygmomanometer. The sensor of the hospital oximeter was placed on the forefinger of the same hand of the tester oximeter. Thus, each patient has his or her own control.

Measurements were carried out prior to anesthesia (admeas 1), every 15 min during the one-hour surgery (admeas 2, admeas 3, admeas 4, admeas 5) and, at the end of the surgery (admeas 6). All measurements were developed in acclimated operating rooms, at the same room temperature and standard illumination. The values presented by the tester oximeter were compared to those obtained from the hospital oximeter. With the purpose of verifying whether both oximeters agreed in the measurement of oximetry variable and assuring they were not presenting significant statistical difference, the Pearson Correlation and the Bland and Altman method were used.[9]

RESULTS

The average age of the patients was 52 years. Among them, 36 were female and 22 were male. The predominant race was Caucasian followed by African and Asian, representing 35, 20, and 3 patients, respectively.

The combined measurements were developed by both oximeters, the tester and the control, in each patient and along the established period was referred to as a "pair." Each pair was observed simultaneously for 1 min to accurately determine the values indicated in their respective monitors. The ratio between the oximetry values from the tester and control devices along each surgical period is described in Table 1. It is possible to verify the proximity of minimal and maximal values and the average checked between them. The difference between such values was not statistically significant ($P < 0.05$).

Table 1: Description of the oximetry variable, separated by type of oximeter in every surgical time (time admeasurements 1, 2, 3, 4, 5, and 6)

Time	Fixed oximeter with dräger monitor (control)				Portable oximeter fingertip MD300C3 (test)			
	Average	S.D.	Minimal	Maximal	Average	S.D.	Minimal	Maximal
1	98.26	0.83	96	99	98.02	0.98	96	99
2	98.66	0.81	96	100	98.33	0.94	95	99
3	98.69	0.75	97	100	98.43	0.80	96	100
4	98.88	0.68	97	100	98.62	0.75	97	100
5	98.90	0.58	98	100	98.71	0.53	97	100
6	98.86	0.54	98	100	98.76	0.47	98	100

S.D=Standard deviation

Table 2 illustrates the interpretation of the Pearson Correlation Coefficient (r), which is a measurement of linear association that varies from –1 to 1. The signal [positive (+) or negative (–)] indicates a positive or negative direction of the relationship, and the value suggests the strength of the relationship between the variables. A perfect correlation (–1 or 1) indicates that the score of a given variable could be determined exactly when knowing the score of the corresponding variable. On the other hand, a correlation of value zero indicates that there is no linear relationship between the variables. The Pearson Coefficient was between 0.8265 and 0.8785, suggesting a strong positive correlation between tester and control devices; this suggests an agreement between them.

The Bland and Altman method[9] permitted calculation of the agreement limit between the values admeasured by the oximeters for each evaluated period. For devices in accordance with their measurements, the values of the difference between them should be close to zero. Figure 1 presents the Bland and Altman analysis which compares the oximeters at different measurements. It is possible to observe the proximity of average with the zero value, suggesting agreement between both devices. Figure 1 demonstrates the average of the agreement limit in the measurement intervals during the surgeries. The average of comparative analysis presented by the devices was 0.2337 ± 0.4355 (mean ± SD), suggesting a strong correlation between the obtained results.

Table 2: Interpretation of pearson correlation coefficient

Correlation coefficient	Correlation
r=1	Perfect positive
0.8 ≤ r<1	Strong positive
0.5 ≤ r<0.8	Moderate positive
0.1 ≤ r<0.5	Weak positive
0<r<0.1	Lowest positive
0	Null
0.1<r<0	Lowest negative
0.5<r≤ 0.1	Weak negative
0.8<r≤ 0.5	Moderate negative
1<r≤ 0.8	Strong negative
r= –1	Perfect negative

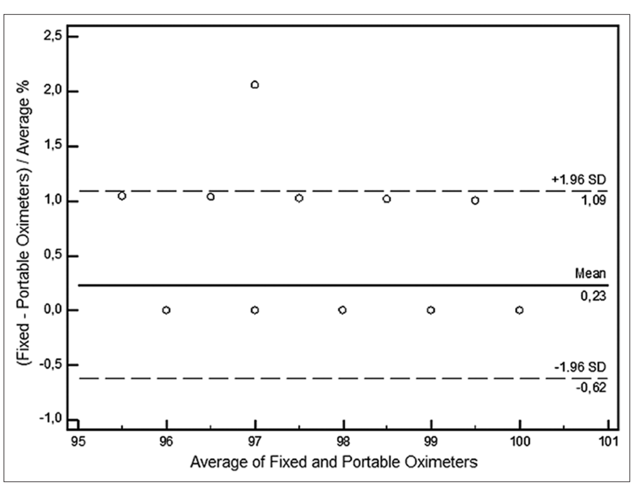

Figure 1: Bland and Altman analysis comparing the fixed (with Dräger monitor) and portable oximeters, independently from admeasurements

DISCUSSION

The availability of a method is able to estimate the peripheral oxygen saturation levels in a continuous and effective way represents an attractive perspective to different healthcare professionals, especially since this variable is useful for monitoring patients receiving treatment. Pulse oximetry is a noninvasive and safe method of checking SpO2, and it was accepted as a clinical standard during anesthetic intraoperative monitoring.[10] The pulse oximeters' functioning is based on the fact that oxyhemoglobin and deoxyhemoglobin differ in the transmission of red and infrared light. In the oximetry and plethysmography the arterial blood volume in the tissues and light absorption by blood suffer an alteration during the pulsation that is always related to a given value of SpO2.[11,12]

The administration of local anesthetics in medical and dental procedures can cause stress and systemic disturbances in some patients. The increase in cardiac frequency and the vasodilation of skeletal musculature arteries could represent cardiac effects of adrenalin increase, induced by its effect on beta 1 and beta 2 receptors. The clinical manifestation of such effects could be the increase of systolic and decrease of diastolic blood pressures. Psychological stress can produce effects similar to those produced by physical changes, such as when activation of the sympathetic system and hypothalamus-hypophysis-adrenal axis occurs. Situations involving pain and anxiety increase the activity of this system, which consequently increases the secretion of cortisol.[13,14] Occasionally, in simple and painless dental procedures, the algophobia (fear and pain) can increase anxiety and create stress situations that may result in cardiac and respiratory alterations.[13] In order to avoid such potential reactions, it is essential to monitor patients' vital signs.

The efficacy of this study's test oximeter is suggested by the proximity between tester and control data [Table 1], where the minimal, maximal, and average obtained values are presented in the face of their corresponding values achieved in the control device. When the values between minimal and maximal do not coincide, the differences were at most 3%, well within the standards accepted by other authors.[5,15-17] In the found saturation averages, there was no statistically significant difference at $P < 0.05$.

Fukayama and Yagiela[10] described the important benefits from the "monitoring practice" in dental procedures, as it functions as an aid to dentists: (1) enabling them to detect acute medical emergencies requiring immediate intervention, (2) improving their perception of pictures that could result in irreversible damage if not immediately assisted and, also, (3) supporting them in the evaluation of a patient's vital signs with higher accuracy, thus decreasing the potential risks of any possible emergency.

By means of the values comparison, it was possible to verify how much the measurements from the tester device were similar to those from the control device, with a coincidence of 100% in the majority of developed admeasurements and a difference inside the standard deviation described in the literature previously.[5,14,17-19] Utilizing the Bland and Altman method to compare the time averages in every device, the proximity of zero in the found values (minimal 0.1043 ± 0.0228 and maximal 0.3339 ± 0.2070; mean ± SD) was verified [Figure 1]. The general average of the comparison of values admeasured by both oximeters suggests agreement between these involved devices.

The SpO2 values in this study ranged from 95 and 100% of saturation. The accuracy found between the used devices corroborates a study developed by Grundmann *et al.*[19] that evaluated the performance of six simultaneous pulse oximeters in 20 individuals in which statistically significant differences were not found between the admeasurements of the tested devices.

The oxygenation rate should be independent of individual skin color, presence of nail polish, dirt, or jaundice.[5,6,17-19] However, some factors affect the performance of devices, such as patient movements, mainly in the area on which the oximeter is placed,[6] low blood flow to sensor area, as well as sensor adherence to skin.[1,19] The negative implication of these factors is the occurrence of false alarms of hypoxia, which is a behavior well-described in the literature, understood as a limitation of fingertip sensor pulse oximeters.[2,4,6,20-22]

Some oximeters, such as those manufactured in the United States of America, are tested by regulatory agencies such as the Food and Drug Administration (FDA). These organizations certify device efficacy between 70 and 100% of saturation, with approximate standard deviation of ± 3%.[5] It is also mentioned by some authors that occasional delays in the measurement, or the lack of SpO2 values indicated simultaneously by different devices, likely do not present clinical significance.[18,21] However, according to Batchelder and Raley,[21] there is not a standard reference to calibrate the pulse oximeters, and there is no other accepted method to verify their correct calibration, other than their direct testing in humans.

The easy device handling and its portability allows widespread and flexible use, limiting the need to purchase more complex and high cost equipment, which would not be viable for use in dental offices, especially in developing countries.

In basic dental care, the verbal contact between the dentist and his patient is essential for monitoring the function of patients' central nervous systems. This requires only simple and short answers during attendance, without any interruption for the dental treatment. Unfortunately, professionals frequently dedicate excessive attention to the procedure, not establishing such contact with their patients or simply neglecting it.[13] As a general rule, the use of pulse oximeters is essential for monitoring an individual's vital signs while it is under attendance, and it would avoid further intercurrences.

Our results suggest an agreement between the values presented by tester oximeters, in terms of those from control oximeters and in the monitoring of patients' vital signs. Further studies are suggested regarding oximetry in dentistry, considering that there are only a small number of studies in the literature concerning this subject.

CONCLUSION

According to the methodology of the research, the portable fingertip pulse oximeter has similar accuracy to the conventional hospital oximeter with digital sensor. The PPO can be used in dental treatments.

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