IRB Research Proposal

Study Title: The Impact of Skin Tone on Pulse Oximeter Accuracy

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Abstract

Background: Pulse oximeters work by the principle of photo-spectrometry and rely on the interaction between light and saturated and unsaturated hemoglobin. Pulse oximeters allow for the rapid assessment of oxygen saturation in a non-invasive manner, but accuracy of the oxygen saturation is of concern.. Previous studies have called attention to the lack of accuracy in pulse oximeter readings when considering darker skinned patient populations. This lack of accuracy is often referred to as occult hypoxemia, or hypoxemia occurring when the measured oxygen saturation of the pulse oximeter is higher than the arterial oxygen saturation measured by blood gas analysis. Previously conducted studies had relied on self-report of skin tone values that are subjective and not rigorously define or validated, making it difficult to determine the exact role skin tone plays in pulse oximeter readings. The goal of this study is to determine what specific role skin tone plays in influencing pulse oximeter accuracy.

Methods: This will be a prospective cohort study at Rush University Medical Center. Patients considered for the study will be adult patients over the age of 18 who have been admitted to the ICU, general medicine/surgery wards, or visiting the pulmonary function labs and/or outpatient pulmonary services clinics at Rush University Medical Center and have an order for ABG analysis. When the patient is having an arterial blood gas drawn for clinical reasons, two pulse oximeters (representing the most common models) will be used to obtain oxygen saturation values, and the SpO_2 value from the bedside monitor will be recorded as well. Subjective skin color samples data will be determined using the Monk scale as a reference and recorded. A Konica Minolta CM-700d spectrophotometer will also be used to objectively determine skin tone. Data will be uploaded to a secure REDCap server and statistical analysis will be conducted using SPSS 22.0 software for windows systems.

Introduction

Pulse oximeters are diagnostic tools that, allow for the calculation of oxygen saturation values based on the consistent and predictable way light of specific frequencies (660nm and 940nm) interacts with hemoglobin.[1] Pulse oximetry conveniently allows clinicians to noninvasively monitor oxygen saturation in real time as an alternative to invasive arterial blood gas analysis, which is measured from a sample of arterial blood from an intermittent arterial blood draw or from an indwelling arterial catheter.[1,2] The significance of pulse oximetry is profound, as it is commonly used in virtually every patient care area from outpatient clinics to emergency rooms, operating rooms, and intensive care units. [3]

Pulse oximeters obtain readings by measuring the amount of projected light that is reflected to the sensor. Blood cells that are desaturated absorb more light from the 660nm light source and blood cells that are saturated absorb more light from the 940nm light source. These reflected values (the light rays that were not absorbed) are recorded. Using the Beer-Lambert law the ratio of the two values is calculated and used to determine the oxygen saturation of the blood.[1] Due to the optical nature of the device (using light and the readout from the photosensor to obtain data) pulse oximeters are susceptible to error if interference exists between the sensor and the patient skin.[4] Errors in pulse oximetry have been a known issue with pulse oximeter results for some time, with articles being published in the early to mid-1990's reporting on the effects of skin pigmentation impacting accurate saturation values.[2,5] Clinically, this issue is significant as occult hypoxemia could impact clinical decisions and is potentially harmful to patients. In 2020, Sjoding et al[5] noted that pulse oximeters had an average variance of 3.6% in patients with light skin tone and 11.4% average variance in patients with dark skin tone. They suggested that the rate of occult hypoxemia is three times higher in black patients than in white

patients. Similarly, Valbuena et al[6] used de-identified data from the Extracorporeal Life Support Organization (ELSO) registry to determine if pulse oximetry is less accurate in non-White adult patients undergoing extracorporeal membrane oxygenation (ECMO) for respiratory failure. They concluded that occult hypoxemia is more prevalent in Black patients when compared to White patients about to undergo ECMO for respiratory failure. They also noted that pulse oximetry has limitations and racially differential usefulness in evaluating hypoxemia for patients in acute respiratory failure. Through spectroscopic analysis of heavily pigmented skin, it was revealed that an increase in skin pigmentation resulted in lower transmission of light at a frequency of 700nm.[7] Further, a recent large, observational study of prospectively collected data from critically ill adults receiving invasive mechanical ventilation examined 5,557 paired measurements of invasively measured SaO_2 with a SpO_2 measured within 10 minutes and found the incidence of hypoxemia was three times greater among Black patients compared with White patients, and hyperoxemia (PaO2 > 150 mm Hg) was present twice as often among Black patients.[8] These data suggest that inaccuracy of pulse oximeters in darker skinned individuals is a result of both statistical bias as well as variance.[8] As a result of these findings, the potential for pigmentation to impact pulse oximeter values warrants further investigation and necessitates increased scrutiny of the color data recorded.[9] To accurately judge color by visual inspection two factors must be present: 1) a calibrated light source that has been rated above 90 CRI (Color Rendering Index), and 2) a calibrated reference viewed under the same light source to judge the color against.[10]

Presently, there is a collective body of literature suggesting that pulse oximetry accuracy is impacted by skin color.[2,5,7,11] As stated by Okunlola et al there has been a renewed interest in pulse oximetry due to the COVID-19 pandemic and the Sjoding paper highlighting the issue.[2,5,8]

In fact, Senators Elizabeth Warren, Cory Booker, and Ron Wyden sent a letter to the United States Food and Drug Administration (FDA) in 2021 urging them to review the interaction between a patient's skin color and the accuracy of pulse oximeters.[2] That said, current studies evaluating pulse oximetry and skin tone are often methodologically flawed, as race itself is used to define patients, and there is often lack of objective data on skin tone available for analysis. Okunlola et al[3] suggests that using race to define patients with dark skin pigmentation is problematic. They propose that standardized, less subjective measures should be used to understand the impact of skin tone on pulse oximeter performance.[10] Additionally, they suggest that objective measures be done at the site of pulse oximeter measurements (e.g., both sides of the fingertip).[2] In addition, the UCSF hypoxia lab, published their protocol for skin color assessment in which they specify the surfaces on the hand best suited for assessment as well as additional scales for measuring these findings.[12] Thus, the purpose of this study is to assess and quantify the discordance between SpO2 and SaO2 values across various skin tones (skin pigmentation groups). The secondary aim of this study will be to determine the impact of various measures such as age, legal sex, reported race, reported ethnicity, reason for admission, SOFA score, blood pressure, heart rate, and respiratory rate have on pulse SpO_2 and SaO_2 discordance.

Experimental Design and Methods

This will be a prospective cohort study at Rush University Medical Center. Patients considered for the study will be adult patients over the age of 18 who have been admitted to the ICU, general medicine/surgery wards, or visiting the pulmonary function labs and/or outpatient pulmonary services clinics at Rush University Medical Center and have an order for ABG analysis. Each subject will only participate once in the study.

For each subject, pulse oximetry saturation values (SpO_2) will be recorded at the same time as the blood drawn for the arterial blood gas analysis (SaO_2). While the patient is having an arterial blood gas drawn, for reasons other than this study, two pulse oximeters: Masimo Rad-G Pulse Oximeter (Masimo Corporation, Irvine, USA) with an averaging time of 8 seconds, and the Medtronic Nellcor Portable SpO_2 Monitoring System PM10N (Medtronic, Minneapolis, USA) with an averaging time of 7 seconds, will be used to obtain oxygen saturation values. The SpO_2 shown on the bedside monitor (Philips, Cambridge, USA) will be recorded as well. Oxygen saturation from the blood sample will be analyzed per institution standard.

Each pulse oximeter will be placed on the patient's index finger and ring finger (making sure that both pulse oximeters tested are on the same hand) with the patient's middle finger separating the two. To reduce the likelihood of light pollution that might impact the results, the pulse oximeter probes will be isolated using gauze or a towel. Pulse oximeter sensors will be applied in advance of data collection in accordance with the averaging time of each respective device, with the value being recorded at the time of the arterial blood gas being obtained.

Skin Tone Assessment: Each subject's skin tone will be determined by using the Monk Scale (Harvard University, Cambridge, USA). This chart will be compared to the skin tone on the index fingernail, the dorsal surface of the fingernail in between the nail bed and the distal interphalangeal joint as well as the palmar surface. To assess skin natural skin tone, we will also assess an area of the body that is typically not exposed to sunlight, like the inner upper arm. Using a Konica Minolta CM-700d (Konica Minolta, 101 Williams Drive Ramsey, NJ 07446 USA) with skin analysis software version 1.4, we will also objectively measure skin tone at the index fingernail, the dorsal surface of the fingernail in between the nail bed and the distal

interphalangeal joint as well as the palmar surface. To assess skin natural skin tone, we will also evaluate an area of the body that is typically not exposed to sunlight, like the inner upper arm.

Inclusion criteria:

1. Adult patients over the age of 18
2. Patients admitted to an intensive care unit, general medicine/surgery wards, or visiting the pulmonary function labs and/or outpatient pulmonary services clinics at Rush University Medical Center
3. Patient has an existing order for an arterial blood gas analysis [arterial line or puncture]

Exclusion criteria:

1. Patients with heavy scar tissue on the sensor site
2. Patients with hand tremors
3. Opaque nail polish that cannot be removed

Study outcomes

The primary study outcome is the discrepancy between SpO_2 and SaO_2 in patients with light and dark skin tone. Skin tone will be considered light for patients with Monk Scale between A-G, and dark for patients with Monk scale between H-J. The secondary aim of this study will be to determine the impact of various measures such as age, sex assigned at birth, reported race, reported ethnicity, reason for admission, SOFA score, blood pressure, heart rate, and respiratory rate have on pulse SpO_2 and SaO_2 discordance.

Data collection

Data collection will be done by directly obtaining the pulse oximeter saturation data while the participant is having a blood gas sample taken. The SaO_2 value will be obtained from the arterial blood gas that is routinely analyzed by the central lab at Rush University Medical Center. Data will be entered into REDCap (Version 11.2.4, Vanderbilt University, Nashville, USA) secure database.

Baseline information gathered will include demographic information (age, legal sex, race, ethnicity, reason for admission), pulse oximeter saturation data, skin tone assessed via Monk scale, SOFA score, blood pressure, heart rate, respiratory rate, oxygen device, F_IO_2 or oxygen flow, perfusion index, stability of SpO2 reading, quality of SpO2 waveform, vasopressor use and dose, and ABG source [arterial line or puncture].

Sample size

This study is a two-group comparison study designed to compare the discrepancy of SpO_2 and SaO_2 in patients with dark and light skin tone. In the study by Foglia et al,[13] the discrepancy of SpO_2 and SaO_2 in patients with dark skin pigment was reported as a mean of 5.4%, a standard deviation of 5.1%, while a mean of 3.0%, a standard deviation two of 5.0% for patients with light skin pigment. With an effect size of 0.48, the number of participants that will be enrolled in our study is 140.[14]

Data analysis

Data will be recorded manually and saved in a secure REDCap (Version 11.2.4, Vanderbilt University, Nashville, USA) server. Identifiable data such as medical record number and birthdate with be collected, but only deidentified data will be shared outside of the immediate Rush research group. . Statistical analysis will be done with SPSS statistics software

(Version 28.0.1, IBM, Armonk, USA). Nominal variables will be presented as frequency distribution. Continuous variables will be presented as a mean with standard deviation or as median with interquartile ranges, based on normality. Bland-Altman analysis will be performed to measure the agreement between the SaO_2 values and the SpO_2 values. The SaO_2 and SpO_2 values between two study groups (light versus dark) will be analyzed with a T-test or the Mann Whitney test, based on normality. SaO_2 and SpO_2 values within a subject will be analyzed using paired T-test or Wilcoxon sign rank, based on normality. The dichotomous variables will be analyzed using chi square and fisher exact tests, as needed. Reported p-values will be two-sided and p-value < 0.05 will be considered significant.

Recruitment and informed consent process

Upon notification of an arterial blood gas order, we will obtain consent from the patient if they have the capacity to do so (fully awake, oriented). If not, we will attempt to seek consent from a legally authorized representative (LAR). For those without the capacity to consent and for whom an LAR is unavailable, the study procedures will be performed and we will seek consent to use the data when the patient regains the capacity to consent. If the individual expires or does not regain the capacity to consent, the data will still be used.

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