ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES DEPARTMENT OF INTERNAL MEDICINE

Inaccuracy assessment of pulse oximeter in black-skinned adults admitted to ICU in Tikur Anbessa Specialized Hospital

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A research Result submitted to the Department of Internal Medicine, School of Medicine, College of Medicine and Health Sciences, Addis Ababa University in partial fulfillment of the requirements for the Degree of Subspecialty Certificate in Pulmonary and Critical Care Medicine.

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List of Acronyms and Abbreviations

AA	Addis Ababa
AAU	Addis Ababa University
ABG	Arterial Blood Gasses
ADHF	Acute Decompensated Heart Failure
AKI	Acute Kidney Injury
ALD	Alcoholic Liver Disease
ATN	Acute Tubular Necrosis
CKD	Chronic Kidney Disease
COPD	Chronic Obstructive Pulmonary Disease
CRVHD	Chronic Rheumatic Valvular Heart Disease
DKA	Diabetic Ketoacidosis
DVT	Deep Venous Thrombosis
Dx	Diagnosis
FAD	Food and Drug Administration
GBS	Guillain-Barre Syndrome
HAP	Hospital Acquired Pneumonia
HbA1c	Hemoglobin A1C
HIV	Human Immunodeficiency Virus
HTN	Hypertension
ICU	Intensive Care Unit

IRB	Institutional Review Board
MD	Doctor of Medicine
MDD	Major Depressive Disorder
PaC02	Partial Pressure of Arterial Carbon Dioxide
Pa02	Partial Pressure of Arterial Oxygen
PCCM	Pulmonary and Critical Care Medicine
PH	Potential of Hydrogen
PHTN	Portal Hypertension
PUD	Peptic Ulcer Disease
SAH	Subarachnoid Hemorrhage
SaO2	Arterial oxygen saturation from ABG
SCAP	Severe Community-Acquired Pneumonia
SpO2	Peripheral arterial oxygen saturation
TASH	Tukur Anbessa Specialized Hospital
T1DM	Type1 Diabetes Meletus
T1RF	Type1 Respiratory Failure
T2DM	Type2 Diabetes Meletus
TMNG	Toxic Multinodular Goiter
UGIB	Upper Gastrointestinal Bleeding
UK	United Kingdom
WHO	World Health Organization

Table of Contents

List of Tables

List of Figures

Summary

Background:

The measurement of oxygen saturation via pulse oximeter is a safe and noninvasive method to approximate arterial oxygen saturation (SpO2), which is an important vital sign in clinical assessment [1-3]. According to manufacturers, reported values ranging from 70 to 100 percent are considered accurate within 2 to 3 percent of the true value, as per FDA standards [12,13]. Any variation in oxygen saturation measured by the pulse oximeter (SpO2) compared to the gold standard measurement by Arterial Blood Gas (ABG) measured oxygen saturation (SaO2) of ≥4% is considered inaccurate [12,13]. There have been recent reports of systemic racial bias where pulse oximeter-measured oxygen saturation (Spo2) has been found to overestimate true arterial oxygen saturation (SaO2) in patients with darkly pigmented skin, leading to concerns about the clinical accuracy of pulse oximetry [6]. Though this finding is deeply relevant to Africa, there is no data from Africa including Ethiopia.

Objective: To determine the frequency of Pulse Oximeter inaccuracies in black-skinned adults admitted to the ICU at TASH in Addis Ababa, Ethiopia between July 2023, and February 2024.

Methodology:

We conducted a cross-sectional observational study at a tertiary medical center. While collecting an arterial blood gas, we utilized a pulse oximeter to measure oxygen saturation in the opposite arm. Pulse oximeter readings were recorded after 10 seconds of stable measurement. We used Fitzpatrick skin color tone classification to scale skin color of the patients. Patients with shock, severe anemia, profound hypoxemia and hypothermia were excluded [3, 5,15].

Statistical Analysis

Quantitative analysis was conducted to compare the oxygen saturation estimates obtained from the pulse oximeter with the gold standard measurement from the arterial blood gases. The resulting discrepancies were documented and entered into SPSS for analysis. Descriptive statistics were then employed to determine the mean discrepancy and the prevalence of pulse oximeter error.

Result

During our study, we simultaneously measured SpO2 and SaO2 for 72 patients. 37 patients were excluded due to shock, severe anemia, profound hypoxemia and hypothermia, leaving 35 patients for preliminary result analysis. The skin color of the patients according to Fitzpatric classification (Table1) were Class III (16 patients), Class IV (12 patients), Class V(6patients) and Class VI(1patient). The SpO2 readings taken by pulse oximetry showed that 31 patients (88.6%) had SpO2 ≥ 92%. Among the 4 patients who had SpO2 of <92%, 2 (5.7%) had SpO2 between 88-< 92%, 1(2.9%) had SpO2 between 80-<88%, and 1 (2.9%) had SpO2 between 70-<80%. On ABG, we found that 17 patients (48.8%) had SaO2 readings of <92%. 16 patients (45.7%) had a pulse oximeter inaccuracy/error. The mean discrepancy of SpO2 to SaO2 was 5.4666 (SD= ± 8.39870, range=-4.8 to 33.4). The prevalence and mean discrepancy percentages of pulse oximeter error at different ranges of SpO2 sequentially were as follows: SpO2 ≥ 92% (38.7%,4.95), 88-<92 % (100%,6.95%), 80-<88% (100%,5.6%), and 70-<80% (100%, 29.4%). Even if the proportion of patients with SpO2 <92% is low, this study indicated that mean discrepancy might be even more as saturation drops.

Discussions and Conclusion:

The results indicate a higher frequency/prevalence of error compared to other studies conducted in different settings, which reported 11.7% (7) and 17% (9) prevalence of pulse oximeter error in black patients.

While these preliminary findings suggest that the pulse oximeter overestimates arterial oxygen saturation relative to ABG-measured arterial oxygen saturation in our sample, it is important to note that a larger sample size is required to draw a more definitive conclusion.

Recommendations

We should be cautious in interpreting SpO2 in Dark-skinned patients, especially when patients have low oxygen saturation. Pragmatic studies with larger sample size are needed to observe differences in Pulse oximeter error across different ranges of SpO2 and skin color classes.

Keywords: ABG, Adult, Black skin, Fitzpatrick classification of skin color tone, ICU, Pulse Oximeter, Pulse oximeter error, SaO2, SpO2.

1: Introduction

1.1Background and Context

The noninvasive measurement of arterial oxygen saturation (SpO2) using a pulse oximeter is a critical clinical evaluation [1–3]. The Food and Drug Administration (FDA) mandates accurate testing of pulse oximeters against SaO2 in healthy adults in laboratory settings [4]. Reliable assessments of arterial oxygen saturation (SaO2) are vital in clinical decision-making, including hospitalization, ICU admission, and supplemental oxygen therapies, such as non-invasive and invasive mechanical ventilation. The Covid pandemic has renewed interest in the measurement error of pulse oximetry in estimating oxygen saturation, which has been noted for many decades [6]. Furthermore, concerns have been raised about the accuracy of pulse oximetry, specifically the overestimation of true arterial oxygen saturation (Sao2) in individuals with darkly pigmented skin, leading to reports of racial bias. Recent research found that hidden hypoxemia was almost three times higher among patients who self-reported as black compared to those who self-reported as white in a large cohort study [6,7]. The direction of the error is concerning, as it is likely to lead to spuriously high oxygen saturations which may delay the treatment escalation in patients with darker skin tones. There have been no data from African countries to date, and no data to mention from Ethiopia.

1.2 Statement of the Problem

Pulse oximetry is a widely used non-invasive tool for measuring oxygen saturation in critically ill patients. However, recent studies have suggested that pulse oximeters may be less accurate in Black individuals compared to other racial groups due to differences in skin pigmentation and other biological factors. This inaccuracy could lead to delayed or inappropriate interventions in critically ill Black patients, posing a significant risk of morbidity and mortality. Several real-world studies since December 2020 suggest individuals with darker skin may be at increased risk of missed diagnosis of hypoxemia, resulting in delays in treatment and worse patient outcomes [4-6]. There have been very few data from African countries to date, and no data from Ethiopia. Ethiopia is known to have more than 80 ethnicities with a wide range of skin color tones. Hence, it is crucial to examine the accuracy of a pulse oximeter in Black critically ill patients at TASH. This study aims to determine the prevalence of pulse oximeter inaccuracies in critically ill patients and to identify contributing factors such as skin color tone, demographics, and clinical and physiological variables. The results of this study will lay the groundwork for additional research in multiple centers throughout the country, for more conclusive findings.

1.3 Research Questions

What is the Frequency of Pulse Oximeter inaccuracy in black-skinned adults admitted to ICU in TASH?

1.4 Relevance and Importance of the Research

Pulse oximeters are commonly used in hospitals to measure the oxygen levels in a person's blood. However, recent studies have shown that these devices may not always provide accurate readings, especially for individuals with darker skin tones. In Ethiopia, no research has been conducted on this issue yet. The results of this study will be used to explore the topic further in multiple centers throughout the country to obtain more conclusive results. These findings could potentially lead to changes in institutional guidelines for determining target oxygen saturation levels in critically ill black adults and prompt a re-evaluation of national guidelines regarding the use of pulse oximeters to measure oxygen levels in critically ill black adults.

2: Literature review

In clinical assessment, pulse oximetry is a commonly used noninvasive method to measure arterial oxygen saturation (SpO2) [1–3]. However, several factors can impact the accuracy of oximeter measurements, including skin pigmentation, movement artifacts, peripheral perfusion, nail polish or acrylic nails, and the degree of hypoxemia [3, 5,15]. To ensure accuracy, the FDA requires pulse oximeters to be tested in laboratory settings against SaO2 in healthy adults [4]. Manufacturers claim that oximeters are accurate to within 2-3% of the true value for reported values between 70-100%, which meets FDA standards [12,13]. Nonetheless, many clinicians feel that the acceptable accuracy cut-off is 80%, which varies according to the pulse oximeter model used. This typically corresponds with an arterial oxygen tension (PaO2) of around 50 mmHg at a pH of 7.4[14].

Although first noted many decades ago, there has been a recent revival of interest in the increased measurement error of pulse oximetry in estimating oxygen saturation. There have been recent reports of racial bias in the clinical accuracy of pulse oximetry, where oxygen saturation measured by pulse oximetry (Spo2) overestimates true arterial oxygen saturation (Sao2) in patients with darkly pigmented skin. In large cohorts, it was found that Black patients were almost three times more likely to have hidden hypoxemia than white patients [6,7]. For instance, an oxygen saturation of 92 to 96% on pulse oximetry showed an arterial blood gas oxygen saturation of less than 88% in 160 of 939 measurements in Black patients (17.0%; 95% CI, 12.2 to 23.3) [7,8]. Real-world studies published since December 2020 suggest that there is an increased risk of missed diagnosis of hypoxemia, delays in treatment eligibility decisions, and worse patient outcomes among subjects with darker skin pigmentation [9-11].

There was no available study from Africa, and there was no data to mention from Ethiopia. Therefore, it was crucial to critically investigate the inaccuracy of pulse oximeters in Black critically ill patients at TASH.

3: Objective (s)

3.1 Primary Objective

To assess the Frequency of Pulse Oximeter inaccuracy in Black skin adults admitted at ICU TASH, Addis Ababa, Ethiopia from July 2023 to February 2024.

3.2 Secondary objective

To assess Pulse Oximeter Inaccuracy at different ranges of SpO2 and different skin color tones.

4: Methodology

4.1 Study Design and Setting

- This was a cross-sectional Observational Survey conducted in a Tertiary Centre.
- TASH is the biggest specialized and teaching hospital, located in Addis Ababa city. It provides services for more than 700,000 patients per year. It has more than 700 beds and it serves as a training center for undergraduate and postgraduate students including a residency in Internal Medicine and Surgery, Fellowship in PCCM, and other subspecialties (From the AAU website). The study was conducted in the Adult Medical ICU which is staffed with PCCM Physicians, Anesthesiologists, Critical Care nurses, and others. It has a total of 6 beds with 6 mechanical ventilators and monitors. 300-400 hundred adult critically ill medical patients are admitted per year (ICU Logbook).

4.2. Participants/Study Population

- Study population:
  - ✓ All Adults admitted to the Intensive Care Unit, Tikur Anbessa Specialized Hospital, Addis Ababa from July 2023 to February 2024 for whom an arterial blood gas measurement was done.
- Inclusion criteria
  - ✓ All adults of age ≥18 years old who are admitted to ICU, TASH
- Exclusion criteria
  - ✓ SPo2 < 70%
  - ✓ severe hypotension (BP<90//60 and Peripheral Pulse not palpable)
  - ✓ Hypothermia (Temperature less than 35-degree centigrade)
  - ✓ Hemoglobin < 5gm/dl

4.3. Variables

Measured variables of primary interest were SpO2, SaO2, and Skin color by Fitzpatric classification. Age, Sex, Temperature, Blood pressure, and pulse at the time of ABG were also recorded.

Other data that were collected are the Date and time when ABG was done, Admission Diagnosis and hospital number, Comorbidities, Hemoglobin level, Brand, and model of ABG Machine used, and Brand and model of pulse oximeter used to measure the oxygen saturation.

4.4. Methods for Data Collection and Quality Control:

For data collection, we obtained arterial blood samples from all adult ICU admissions upon arrival or whenever it was necessary. During arterial blood gas collection, a pulse oximeter measurement was taken from the opposite arm that was not utilized for the ABG. Oxygen saturation levels were noted after the reading stabilized for 10 seconds.

We used Epoch ABG machine and BLT fingertip Pulse oximeter. To ensure quality control, the pulse oximeter and ABG machine were recalibrated according to the manufacturer's instructions. We had trained Internal Medicine Residents and PCCM Fellows collecting the data and it was supervised by the principal investigator.

4.5. Operational Definitions

- ✓ **SpO2**: Peripheral capillary oxygen saturation, with a normal range of ≥92% for healthy adults.
- ✓ **SaO2**: Arterial oxygen saturation from ABG
- ✓ **Pulse oximeter Error** (Inaccurate): Discrepancy of SpO2 and SaO2 ≥ 4%
- ✓ **Accurate**: Discrepancy of SpO2 and SaO2 within 2-3%
- ✓ **Disparity of SpO2 and SaO2 at different level**: 70-79 %,80-87 %,88-91% and ≥ 92%
- ✓ **Pulse oximeter**: A medical device used to measure the oxygen saturation level (SpO2) in someone's blood from the body's surface.
- ✓ **ABG**: A medical device used to measure the oxygen saturation level (SaO2) from a blood sample taken through arterial puncture.
- ✓ **Skin color**: Fitzpatrick classification of skin type from I to VI

Table 1. Fitzpatrick

Type I	Type II	Type III	Type IV	Type V	Type VI
White Skin. Always burns, never tans	Fair skin. Always burns, and tans with difficulty.	Average skin color. Sometimes mild burn, tan about average.	Light brown skin rarely burns. Tans easily.	Brown skin never burns tans very easily	Black skin heavily pigmented never burns, and tans very easily.
					

4.6. Statistical Analysis

Sample size determination.

Given that we did not have prior information on the prevalence in the setup or similar setup, we included all illegible patients during the study period.

Statistical analysis

We compared the estimates of oxygen saturation from the pulse oximeter (SpO2) with the gold standard measurements from arterial blood gases (SaO2). Data was entered into SPSS and Descriptive Statistics was used to calculate the mean discrepancy and prevalence of Pulse oximeter error. We also calculated the prevalence of Pulse oximeter error (SpO2 vs SaO2>=4) and mean discrepancy at different SpO2 ranges, skin color class, and Hemoglobin range tone.

4.8 Ethical Considerations

We received ethical clearance from the Institutional Review Board of the Internal Medicine Department and TASH, AAU. Treating physicians obtained routine verbal consent before arterial puncture for ABG**.**

5. Results:

During the study period, a total of 207 patients were admitted to the Adult Medical ICU. Unfortunately, due to a shortage of ABG cartridges, only 109 patients were able to have an ABG done. Out of those, only 72 had simultaneous measurements of SpO2, and 37 patients were excluded due to hypothermia, profound anemia, profound hypoxia, and shock as outlined above**.** A preliminary result was obtained from the remaining 35 patients who had simultaneous measurements of SpO2 and SaO2. The primary reasons for ICU admission for the 35 patients were Sepsis (10 patients), Type I Respiratory failure (9 patients), Acute Kidney Injury (2 patients), Upper Gastrointestinal Bleeding(2 patients), and others(12 patients). The SpO2 readings from pulse oximetry showed that 31 patients (88.6%) had a measurement of ≥ 92%, 2 patients (5.7%) had a measurement of 88-<92%, 1 patient (2.9%) had a measurement of 80-<88%, and 1 patient (2.9%) had a measurement of 70-<80%. Four (11.4%) patients had a SpO2 measurement of <92% on pulse oximetry (Figure 1). On ABG, 17 (48.8%) patients had a SaO2 measurement of <92% (Figures 1 and 2). The skin color tone of the patients was classified as III (16, 45.7%), IV (12, 34.3%), V (6, 17.1%), and VI (1, 2.9%). The age and sex distribution of the patients are shown in the table. The mean discrepancy between SpO2 and SaO2 was found to be 5.4666 (SD= ± 8.39870, range=-4.8 to 33.4). A total of 16 patients (45.7%) had pulse oximeter errors of ≥ 4% when compared with ABG-measured O2 saturation.

The prevalence and mean discrepancy percentages of pulse oximeter error at different ranges of SpO2 sequentially were as follows: SpO2 ≥ 92% (38.7%,4.95), 88-<92 % (100%,6.95%), 80-<88% (100%,5.6%), and 70-<80% (100%, 29.4%). Even if the proportion of patients with SpO2 <92% is low, this study indicated that the mean discrepancy might be even more as saturation drops.

The percentage of patients with pulse oximeter errors and mean SpO2-Sa2 discrepancies at different skin color tones were as follows: class III (50%, 6.9%), class IV (50%, 5.36%), and class V (50%, 2.4%). There was only one patient with a skin color tone of class VI, and their SpO-SaO2 discrepancy was 2.1% (Figure2). The number of patients in each class was different, making it difficult to compare the discrepancy rate (mean discrepancy) across the group.

6. Discussions

Out of 35 eligible patients, the preliminary results showed that the prevalence rate of pulse oximeter error was 45.7%, with a mean error of 5.466. For patients with SpO2 ≥ 92%, the prevalence of error and the mean discrepancy were 38.7% and 4.95 respectively. Compared to other studies done at different setups, the prevalence of pulse oximeter error in this preliminary result was higher than the reported rates of 11.7% (7) and 17% (9) in black patients.

In most studies, black patients were defined as those who self-identified as black. In our study, as all our patients were black, we used Fitzpatrick skin color classification to analyze the pulse oximeter error difference at different skin color tones (Table 1). The proportion of patients with pulse oximeter error was 50% for those patients having skin color tone class III to V, with a different mean discrepancy rate in each class (Figure 2). The number of patients in each class was different, making it difficult to compare the discrepancy rate (mean discrepancy) across the group.

7: Strength and Limitations

Strength

It is a prospective study

It was the first of its kind to look at pulse oximeter errors in black skin critically ill patients in the study area and the country.

The limitations:

It is a prevalence/frequency study.

Small sample size for preliminary analysis

8: Conclusion

While the study indicate that the pulse oximeter overestimates arterial oxygen saturation relative to ABG-measured arterial oxygen saturation, it is important to note that a larger sample size is required to draw a more definitive conclusion.

9: Recommendation

We should be cautious in interpreting SpO2 in Dark-skinned patients, especially when patients have low oxygen saturation. Pragmatic studies with larger sample size are needed to observe differences in Pulse oximeter error across different ranges of SpO2 and skin color classes.

Table 2: Demographic Characteristics of the Patients					
Age	Number & percentage	**Sex**	Number & percentage	**Address (Region)**	Number & percentage
20-30	10(28.6%)	M	16(45.7%)	Addis Ababa	13(37.1%)
31-40	7(20%)			Oromia	8(22.8%)
41-50	8(22.9%)			Amhara	6(17.1%)
≥ 51	10(28.6%)	F	19(54.3%)	SNNP	5(14.3%)
				Tigray	3(8.6%)
Total	35(100%)		35(100%)		35(100%)

Table 3: Clinical Diagnoses of the Patients			
S. N	**Reason for ICU Admission**	**Underlying lung Diseases**	**Other Comorbidity**
1	Acute Severe Asthma	Asthma	NO
2	GBS	NO	NO
3		NO	NO
4	T1RF Secondary to SCAP	NO	AKI/CKD with Uremia
5	T1RF Secondary to HAP	NO	Post operation
6	Pyogenic Meningitis	No	NO
7	Pyogenic vs TB Meningitis	NO	NO
8	T1RF Secondary to HAP	Bronchiectasis	NO
9	T1RF Secondary to SCAP	COPD	NO
10	T1RF Secondary to Sepsis of Chest Focus	NO	HIV/CRVHD
11	ADHF precipitated by? Sepsis Chest of chest focus	NO	CRVHD
12	T1RF Secondary to Sepsis of Chest Focus	NO	Rectal ca
13	T1RF Secondary to HAP	NO	Preeclampsia
14	Post Cardiac Arrest	Lung mass	NO
15	Septic Encephalopathy	COPD	NO
16	Coma Secondary to Drug overdose	NO	MDD
17	UGIB Secondary to variceal bleeding Secondary to PHTN Secondary to ALD	NO	NO
18	T2RF Status Asthmaticus	Asthma	NO

Table 3: Clinical Diagnoses of the Patients			
S. N	**Reason for ICU Admission**	**Underlying lung Diseases**	**Other Comorbidity**
19	T1RF Secondary to HAP vs Pulmonary edema	No	Multiple myeloma
20	Sepsis of chest focus	Asthma/COPD	NO
21	Thyroid storm	NO	TMNG, HIV, HTN
22	Transverse myelitis	NO	DVT
23	Head injury	NO	NO
24	AKI Secondary to Septic ATN	NO	T2DM
25	Massive hemoptysis Secondary to a ruptured hydatid cyst of the lung	NO	NO
26	SAH/Monitoring	NO	HTN, CKD
27	Severe DKA	NO	T1DM
28	Sepsis	NO	HTN
29	Sepsis of Chest focus	No	Pancytopenia Secondary to?
30	Post-partum puerperal sepsis	NO	NO
31	UGIB Secondary to PUD	NO	NO
32	Postop (TAH AND SOP) with Sepsis	NO	NO
33	AKI	NO	NO
34	Severe Preeclampsia	NO	NO
35	Sepsis of chest focus	NO	NO

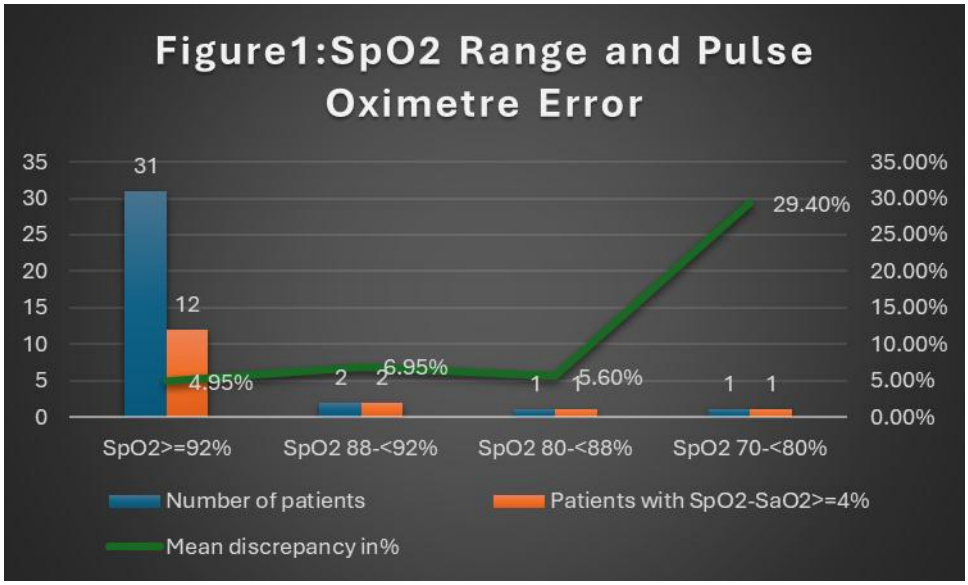
Figure1:SpO2 Range and Pulse Oximetre Error
35
30
25
20
15
10
5
0
35.00%
30.00%
25.00%
20.00%
15.00%
10.00%
5.00%
0.00%
31
12
4.95%
2
2
6.95%
1
1
5.60%
1
1
29.40%
SpO2>=92%
SpO2 88-<92%
SpO2 80-<88%
SpO2 70-<80%
Number of patients
Patients with SpO2-SaO2>=4%
Mean discrepancy in%

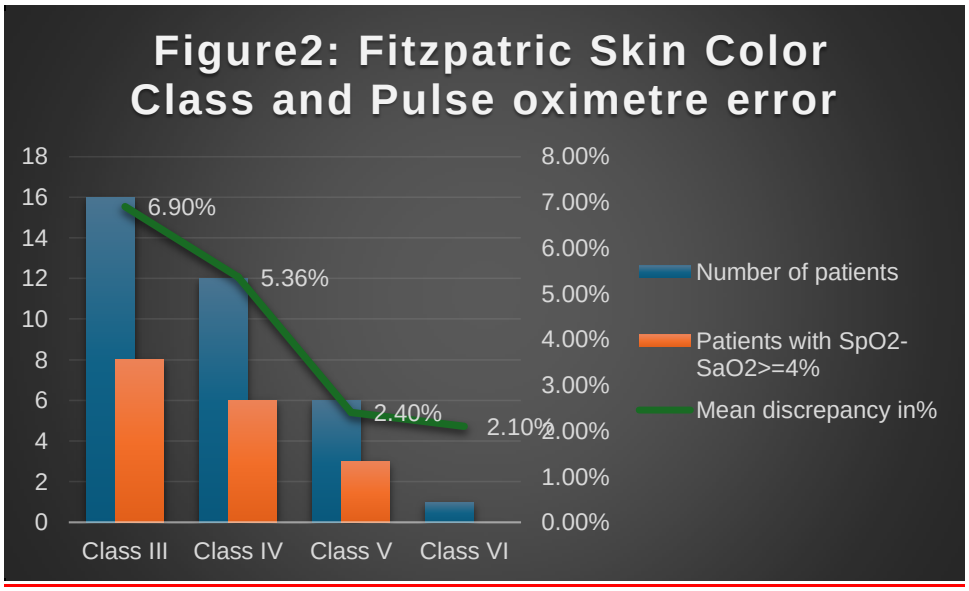
Figure2: Fitzpatric Skin Color Class and Pulse oximetre error
18
16
14
12
10
8
6
4
2
0
8.00%
7.00%
6.00%
5.00%
4.00%
3.00%
2.00%
1.00%
0.00%
6.90%
5.36%
2.40%
2.10%
Class III
Class IV
Class V
Class VI
Number of patients
Patients with SpO2-SaO2>=4%
Mean discrepancy in%

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11: Appendixes

Annex-I: Hospital consent form.

This study will be conducted at TASH, the biggest tertiary hospital in Addis Ababa city. The primary objective of the study is to determine the frequency of Pulse Oximeter inaccuracy in Black-skinned adults who were admitted to ICU TASH in Addis Ababa, Ethiopia, from July 2023 to February 2024. In recent times, there have been reports of systemic racial bias where oxygen saturation measured by pulse oximeter (Spo2) overestimates true arterial oxygen saturation (Sao2) in patients with darkly pigmented skin. This has raised concerns about the clinical accuracy of pulse oximetry [6]. Since December 2020, additional real-world studies have been published, suggesting an increased risk of missed diagnosis of hypoxemia (known as "occult hypoxemia"), delays in treatment eligibility decisions, and worse patient outcomes among subjects with darker skin pigmentation [9-11] . There is no similar study from Africa and no data to mention from Ethiopia. This study seeks to evaluate the prevalence of pulse oximeter error in Black critically ill patients and to identify factors that may impact this error, including demographic, clinical, and physiologic variables. The study findings will serve as a basis for further studies in multiple centers in the country for more conclusive results. This may change institutional guidelines for setting target oxygen saturation for black critically ill adults and lays the ground for reconsideration of national guidelines on the issue of oxygen target by pulse oximeter in black-skinned critically ill adults.

The study involves arterial blood gas measurement which involves arterial puncture which is a painful procedure with almost no chance of any complications. It is done only for patients who are considered to require an arterial blood gas measurement as part of their optimal clinical care. Verbal informed consent is needed as routine ICU care for the procedure by treating physicians. When an arterial blood gas is collected, a pulse oximeter measurement will be taken from the other arm that is not being used for the arterial blood gas (ABG). The oxygen saturation will be recorded after the stability of the reading for 10 seconds.

Please note that no personal information of the patients, such as their name or any other identifying details, will be collected during this study. The information generated from the study

will be disclosed in its entirety. Additionally, the confidentiality of any personal information that is collected will be maintained throughout the study process, and unauthorized access to this information will not be permitted. Please be aware that the department has the right to accept or reject the study at any given time.

If you have any questions regarding the planned study or require further clarification from the principal investigator or the institution, please feel free to contact the principal investigator in person or by telephone at 0911059832 (Jafar Mahammed, principal investigator). If you would like to proceed with the study at this hospital, please confirm your decision by signing.

The participant department IRB _____Date

Principal investigator_____--Date

Annex-II: Questioners

1. Identification: A. card number: _____Date ABG Done ------
2. Personal identification: Age _____ b, Sex_____
3. Patients: Vital signs A. BP_____B. PR_____C. RR_____D. T-------
4. Diagnosis for ICU admission
    a. Primary Cause for ICU admission_____
    b. Comorbidity: _____
    c. Any previous respiratory Problem_____
5. Skin color using Fitzpatrick classification:
6. Machines are used for oxygen saturation.
    a. Model and brand of Pulse Oximeter machine (including the infrared it uses) _____
    b. Model and Brand of ABG Machine _____
7. Measurements:
    a. SpO2 using Pulse Oximeter_____
    b. ABG result: SaO2_____PO2_____
    c. Hemoglobin level _____

Annex-III: Declaration of Investigators

We the undersigned are the principal investigator and the advisors for this study. We declare that this research proposal is our original proposal, and we will all be actively involved in the conduct of the study.

Jafar Mahammed, MD, Pulmonary and Critical Care Medicine Fellow

Signature _____ Date _____

Dr. Amsalu Bekele, MD, Associate Professor of Medicine and Pulmonary and Critical Care Medicine physician

Signature _____ Date _____

Dr. Hanan Yusuf, MD, MPH, Assistant Professor of Medicine and Pulmonary and Critical Care Medicine physician

Signature _____ Date _____

Dr. Dawit Kebede, MD, Associate Professor of Medicine and Pulmonary and Critical Care Medicine physician

Signature _____ Date _____

Dr. Deborah A. Haisch, MD, Assistant Professor of Medicine and Pulmonary and Critical Care Medicine physician

Signature _____ Date _____

Dr. Amsalu Bitew, MD

Assistance Professor of Medicine and PCCM

Head, Department of Internal Medicine, Addis Ababa University, Addis Ababa, Ethiopia

Signature _____ Date _____