ORIGINAL CLINICAL REPORT

OPEN

Race and the Inaccuracy of Pulse Oximetry With Hypoxemia in a Pediatric Cardiac ICU

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OBJECTIVES: To ascertain the potential effects of hypoxemia and race on pulse oximetry in a population of patients, including those for whom hypoxemia is a normal state secondary to intracardiac mixing in an ICU setting.

DESIGN: Retrospective, observational, cohort study.

SETTING: A single center's pediatric cardiac ICU (CICU).

PATIENTS: Eight hundred forty-one patients undergoing bypass operations during a 52-month period (June 2019–October 2023). Predominantly, patients with congenital heart disease. The median age was 7.1 months with 58% younger than 1 year old and 88% younger than 10 years old.

INTERVENTIONS: Arterial blood saturations, as measured by a hemoximeter, were recorded for all patients after bypass operations. These were time-matched, with high-fidelity, to pulse oximeter values.

MEASUREMENTS AND MAIN RESULTS: The mean oximetric difference, or "pulse oximetry overestimation," was defined as arterial oxygen saturation minus that predicted by pulse oximetry, was greater for Black than for White patients (−3.18% vs. −2.19%, $p = 0.006$). Regression shows a significant effect of Sao_2 on oximetric difference ($p < 0.001$) and mildly significant trend for the categorical race ($p = 0.03$) as well as their composite interaction term ($p = 0.047$). Oximetric difference was exaggerated with increasing hypoxemia. At normal oxygen saturations, the oximetric difference was greater for Black when compared with White patients ($p = 0.002$ for patients with $Sao_2 > 94\%$). This effect if race is not statistically significant at other Sao_2 ranges that are clinically important in patients with intracardiac mixing.

CONCLUSIONS: This study redemonstrates effect of increasing hypoxemia on oximetric difference. Race may have an independent effect on oximetric difference. This adds to the body of literature that has previously suggested that pulse oximetry, relied upon as a vital sign, may introduce explicit race-related bias into the bedside interpretation of a patient's clinical state.

KEYWORDS: bias; congenital heart disease; hypoxia; pulse oximetry; race

Pulse oximetry (Spo_2) is ubiquitous in contemporary inpatient medicine. It provides an easily accessible, low-cost, noninvasive surrogate for arterial oxygen saturation (Sao_2). It is monitored continuously and used to guide clinical decision-making in the pediatric cardiac ICU (CICU).

The typical patient population in the CICU includes a substantial number of children born with congenital heart disease in varied states of repair and/or palliation, including a variety of patients for whom hypoxemia is a normal physiologic state as a result of intracardiac mixing of blood. The performance of Spo_2 in predicting Sao_2 declines with increasing hypoxemia (1–3). The accuracy of pulse oximetry in predicting Sao_2 is also differentially affected by patient race (1, 4–6). The postoperative congenital heart disease population offers an

DOI: 10.1097/CCE.0000000000001237

KEY POINTS

Question: Is there a potentially synergistic effect of hypoxemia and race on the accuracy of pulse oximetry in predicting arterial oxygen saturation in a pediatric cardiac ICU?

Findings: A retrospective, observational cohort study in a single center's pediatric CICU. There is a small, but possibly important, difference in the accuracy of pulse oximetry when indexed by race, and this difference may be modulated by hypoxemia.

Meaning: This further suggests that pulse oximetry, relied upon as a vital sign, may introduce explicit race-related bias into the bedside interpretation of a patient's clinical state. Further prospective and outcomes-linked investigation is necessary.

opportunity to examine both factors as they affect the use of pulse oximetry in a clinical critical care setting.

We present a large cohort of patients from a single center's CICU. We hypothesize that the Spo_2 becomes increasingly inaccurate for predicting Sao_2 with increasing hypoxemia and that race has a differential effect on the accuracy of Spo_2.

MATERIALS AND METHODS

This retrospective cohort study includes patients admitted to a single pediatric CICU between June 2019 and October 2023. The Institutional Review Board at the University of Alabama at Birmingham (UAB IRB) reviewed and approved this study (IRB-300008935, Saturation variation between pulse oximetry and arterial blood gas in congenital heart disease, approved September 6, 2022). All study procedures were followed in accordance with the ethical standards of the UAB IRB along with the Helsinki Declaration of 1975, as most recently amended. Informed consent was waived. All patients admitted had physiologic variables recorded by the Etiometry Data Visualization software (Boston, MA). We interrogated this dataset for all Sao_2 values obtained over this period. These values were paired with corresponding Spo_2 values. Sao_2 was measured directly from a time-stamped arterial blood sample using an ABL90 hemoximeter (Radiometer, Copenhagen, Denmark) located on the receiving unit. Arterial line position was not recorded but was typically radial, femoral, and/or umbilical. Spo_2 was measured using a Nellcor pulse oximeter (Medtronic, Minneapolis, MN) paired with a Carescape monitor (General Electric Healthcare, Chicago, IL). The pulse oximeter was usually placed on an extremity digit. Where available and relevant, the preductal Spo_2 was used in the analysis. The Spo_2 values used in the dataset were time-averaged over 1 minute with 5-second separation between data points to reduce the variability inherent in peripheral pulse oximetry. The degree of overestimation of pulse oximetry was defined as the oximetric difference ($Sao_2 - Spo_2$).

Demographic information was obtained from the hospital electronic medical record and extracted from a unified local database aggregating registry data from the Society for Thoracic Surgeons Congenital Heart Surgery Database and Pediatric Cardiac Critical Care Consortium (PC^4). Demographic data elements included age, sex, weight, and race. Given the power limitations introduced by the small number of other races in the dataset, we limited our dataset to patients with Black or White race (multiple race patients were excluded). We extracted all Sao_2-Spo_2 data pairs over the study period. Race was entered into the electronic medical record (EMR) by an admitting clerk after meeting with the patient and family upon intake to our system. To homogenize the dataset and to eliminate repeat measures, we analyzed only the first Sao_2-Spo_2 data pair acquired on arrival to the CICU after a cardiopulmonary bypass (CPB) case. The acquisition of the data at this specific timepoint is universal at our institution. Patients with more than one bypass operation appear multiple times in the dataset and are considered separately in this analysis, including when multiple bypass operations occurred during one hospitalization.

Data are reported as median and interquartile range for continuous variables. Weight and age are also classified categorically and reported as frequency with percentage. Welch *t* test and Mann-Whitney *U* test are used to test, where appropriate, to test for differences between continuous variables. Chi-square test was used to compare categorical variables.

Linear regression was used to characterize the relationship of oximetric difference to arterial oxygen saturation and race. The regression was graphically

described with an interaction plot, including 95% CIs. We visualized the distribution of oximetric difference using two methodologies. Ridgeline plots were used to show the probabilistic distribution of oximetric difference at a variety of arterial oxygen saturations. The mean of the distribution as well as SE of the mean are reported. A modified Tukey boxplot was used showing the box-and-whisker distribution of oximetric differences in bounded ranges of Sao_2 with notches at the 95% CIs.

We also subdivided patients into groups of Spo_2 ranges and showed the percentage of patients whose Sao_2 fell inside or outside of the predicted range. The ranges chosen were normally saturated (> 94%) as well as ranges commonly used as goals for a variety of mixing physiologies (80–90% and 75–85%). This analysis, graphically displayed in a stacked column format, was designed to illustrate the accuracy of various "clinically important" Spo_2 target ranges by inverting the gold standard (Sao_2) for the clinically available mainstay (Spo_2).

R 4.3.2 (R Core Team, 2023) was used for data processing, statistical analysis and data visualization. In addition to the packages mentioned above the tidyverse (Wickam et al, 2019), lubridate (Grolemund and Wickam, 2011), fuzzyjoin (v0.1.6, Robinson, 2020), and readr (v2.1.5, Wickham, Hester and Bryan, 2024) packages were used for data processing. The epiR (v2.0.74, Stevenson and Sergeant, 2024) and pubh (v1.3.2, Athens, 2024) packages were used to statistical analysis. The ggplot2 (Wickham, 2016), ggridges (v0.5.6, Wilke, 2024), and interactions (v1.1.0, Long, 2019) packages as well as Microsoft Excel (Microsoft, Redmond, WA) were used to data visualization.

RESULTS

We identified 16,073 Sao_2-Spo_2 data pairs representing 1,109 unique patients. We included, in our analysis, 956 data pairs from 841 unique patients acquired on arrival to the CICU after a bypass operation (first postbypass data pairs). The median age was 215.5 (91.75–1576.25) days with 17.8% younger than 30 days old, 57.9% younger than 1 year old, and 88.1% younger than 10 years old. Of the patients analyzed, 30.5% of the patients were Black and 60.4% of the patients were White. **Table 1** provides baseline demographic data indexed by race.

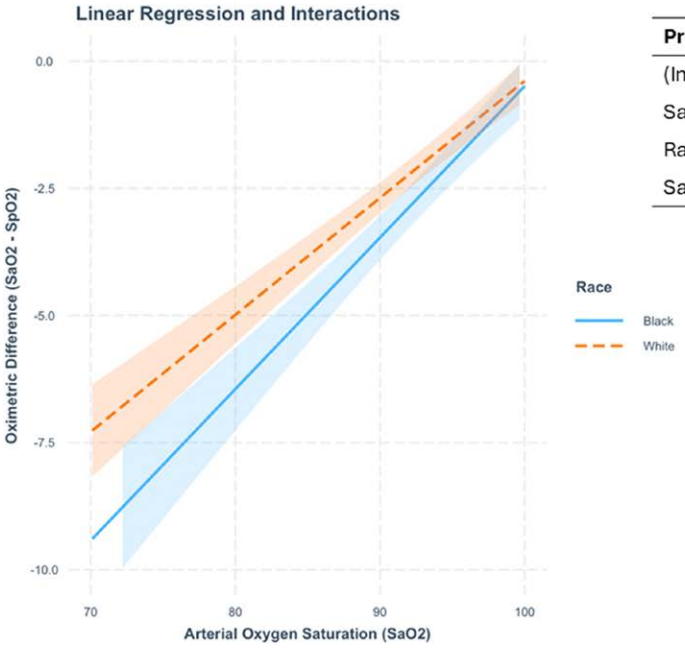
The mean oximetric difference across all first postbypass data pairs was –2.46% (95% CI, –2.74% to –2.19%). The mean oximetric difference for Black patients was significantly greater than the mean oximetric difference for White patients (–3.18% vs. –2.19%, $p = 0.006$).

Figure 1 demonstrates the increasing oximetric difference with hypoxemia. The degree of oximetric difference is modulated by hypoxemia ($p < 0.001$). Race and the composite interaction variable of race and oximetric difference are both mildly significant in the regression analysis. The interaction plot show

TABLE 1.
Demographic Table

Characteristic	White Patients ($n = 577$)	Black Patients ($n = 292$)	p
Gender (female), *n* (%)	246 (42.6)	141 (48.3)	0.01
Age, d	182 (62–1508)	270 (118–1588)	0.01
Age, *n* (%)			
< 1 mo	118 (20.5)	43 (14.7)	< 0.01
< 6 mo	289 (50.1)	120 (41.1)	< 0.01
< 1 yr	346 (60.0)	159 (54.5)	0.01
< 10 yr	512 (88.7)	254 (87.0)	0.24
Weight, kg	6.23 (3.9–15.1)	7.26 (4.6–17.0)	0.02
Weight group, kg, *n* (%)			
< 5	215 (37.3)	86 (29.5)	< 0.01
> 40	56 (22.8)	34 (24.1)	0.49

Data presented as median (interquartile range), and Mann-Whitney *U* and chi-square tests are used to derive *p* values.



Predictors	Estimates	Diff CI	p-value
(Intercept)	-26.63	-30.78, -22.48	<0.001
SaO2	0.26	0.21, 0.30	<0.001
Race, White	4.73	-0.42, 9.88	0.072
SaO2 * White	-0.05	-0.10, 0.01	0.111

Figure 1. Multivariable linear regression with arterial oxygen saturation (Sao_2) and race as independent variables. The oximetric difference increases with decreasing arterial oxygen saturation. The difference may greater for Black than White patients. CIs are at 95%. $Sao_2 < 60$ are excluded from analysis.

divergence of the 95% CIs between SaO_2s of 80 and 90. We excluded, from the regression analysis, a small number (11 data pairs) of extreme outliers with $Sao_2 < 60$. A sensitivity analysis demonstrated further exclusion of outliers based on Sao_2 did not greatly affect the regression analysis.

The distribution of oximetric differences is visualized using ridge line plots (**Fig. 2**) and a modified Tukey boxplot (**Fig. 3**). The oximetric difference increases in the patient groups with greater hypoxemia and is generally greater for Black than White patients.

The additional analysis shown in **Figure 4** describes a clinically targeted approach wherein we evaluated the first postbypass data pairs based on the predicted Sao_2 with respect to clinically relevant Spo_2 ranges. Inpatients expected to have normal saturations, data pairs with an Spo_2 greater than 94% were found to have an Sao_2 less than 94% in 19% of patients and less than 88% in 3.2% of patients. Figure 4 shows the percentage of patients whose Sao_2 fell outside the predicted range by Spo_2. The frequency with which Spo_2 overestimated Sao_2 was greater for Black patients than White patients, but this did not reach statistical significance for the 75–85% and 80–90% Spo_2 ranges. These data ranges do contain overlapping data and were chosen for their clinical relevance. It was rare for patients in our dataset to have an arterial oxygen saturation above the predicted range. The magnitude of inaccuracy of any specific data pair is not analyzed in this figure.

DISCUSSION

This study demonstrates the inaccuracy of pulse oximetry in a pediatric population with congenital heart disease. These inaccuracies are accentuated by the degree of hypoxemia and probably modified by race. Although pulse oximetry is not validated outside of a narrow range (7), it is used to make daily decisions in managing congenital heart disease in both the inpatient and outpatient settings. The increasing inaccuracy of pulse oximetry with hypoxemia may need to be considered when affecting patient management decisions in patients with congenital heart disease. Furthermore, there should be consideration for the introduction of bias into decision-making because patient race likely has a differential effect on accuracy which is supported by our results in the setting of previously published studies.

Our study shows that pulse oximetry generally overestimates arterial oxygen content in a cohort that includes congenital cardiac patients, and that the

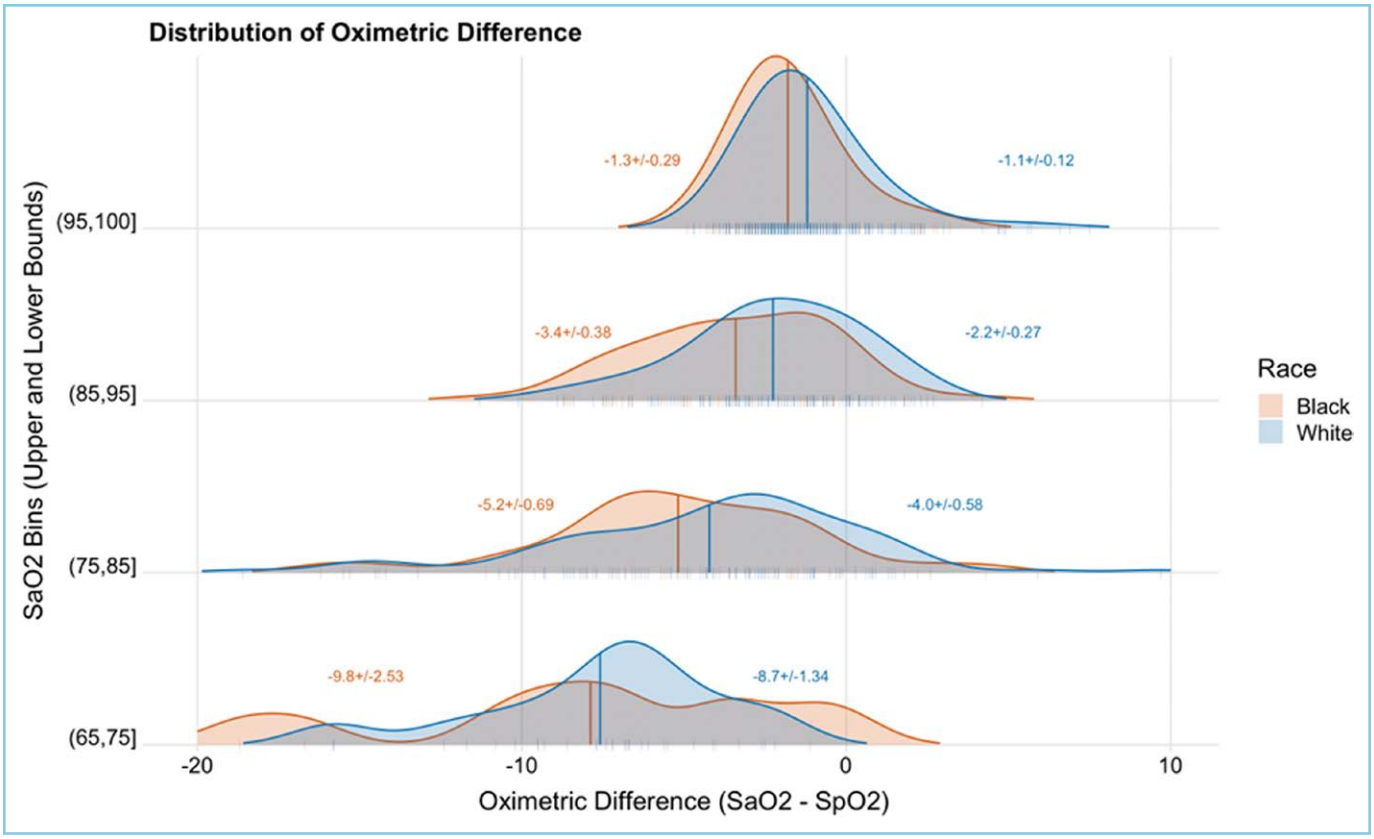


Figure 2. Ridge line plot showing the probabilistic distribution of oximetric differences for groups of data pairs bounded by predetermined, clinically relevant, arterial oxygen saturations (Sao_2). Mean values with SE of the mean are reported in the figure.

degree of this overestimation increases with hypoxemia. This general overestimation trends toward significant difference when categorized by race.

Smaller studies of infants with congenital heart disease have shown impaired pulse oximetry performance in predicting arterial oxygen saturations (1–3, 8). More recently, the COVID-19 pandemic has inspired a multitude of publications regarding the concept of occult hypoxemia (the presence of hypoxemia when pulse oximetry predicts a nonhypoxemic arterial oxygen saturation (9, 10). The findings of our study are important as this is the first large study, including patients with congenital heart disease in a pediatric cardiac ICU where pulse oximetry is used as a routine "vital sign" in bedside decisions. The general overestimation of arterial oxygen content, as confirmed in our study, may lead to false confidence in predicting a patient's true physiologic state. This is especially important in our patients with cyanotic heart disease where the failure to detect critical hypoxemia might affect outcomes.

Savorgnan et al (4) recently published a large, single-center, retrospective study that showed the presence of race-related bias in oximetric difference in a cohort of general PICU patients with COVID-19. Studies in the controlled environment of the catheterization laboratory have been used to demonstrate the impact of hypoxemia on the predictive performance of pulse oximetry among a cohort of single ventricle patients under anesthesia conditions (5, 11). Furthermore, the performance of pulse oximetry is also differentially affected by race and the presence of diastolic runoff (5, 11). Our study adds further data in the immediate post-CPB care setting in the pediatric CICU.

The race-associated bias in oximetric difference may differentially affect decision-making with regard to patient interventions in cyanotic congenital heart disease. We know that outcomes, including mortality, in congenital heart disease are modulated by race (12, 13). Other outcomes, such as neurodevelopment, might also be adversely affected by occult hypoxemia. The potential for explicit technical bias is a modifiable factor. Although our study focuses on inpatients in the immediate postbypass period, we believe that the findings could reasonably be extrapolated to the outpatient world where, while less critically ill, our obligately

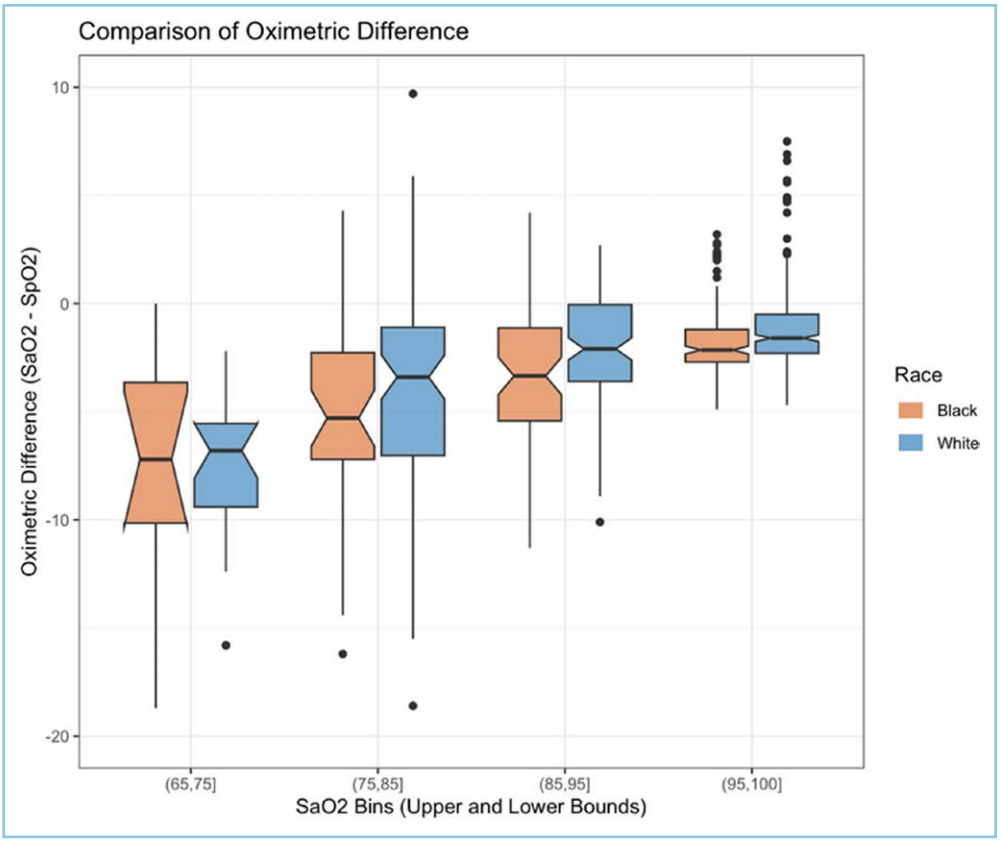


Figure 3. Modified Tukey boxplot showing the distribution of oximetric differences. The "notched boxplot" shows outliers, interquartile range as well as the "notch" showing 95% CI around the median and arterial oxygen saturation (Sao_2).

desaturated patients are subject to an overt reliance on pulse oximetry, a flawed "vital sign," with race-related bias exerting an unknown effect on decision-making and timing of interventions.

This study is limited by its retrospective, single center and observational nature. The ability to detect a significant difference, in some analysis, may be limited by sample size. We performed averaging of the Spo_2 values as there was no way to retrospectively analyze the pulse oximeter waveform and this decision may affect the accuracy of our analysis. We could not ascertain the physical position of the pulse oximeter for each patient. When two pulse

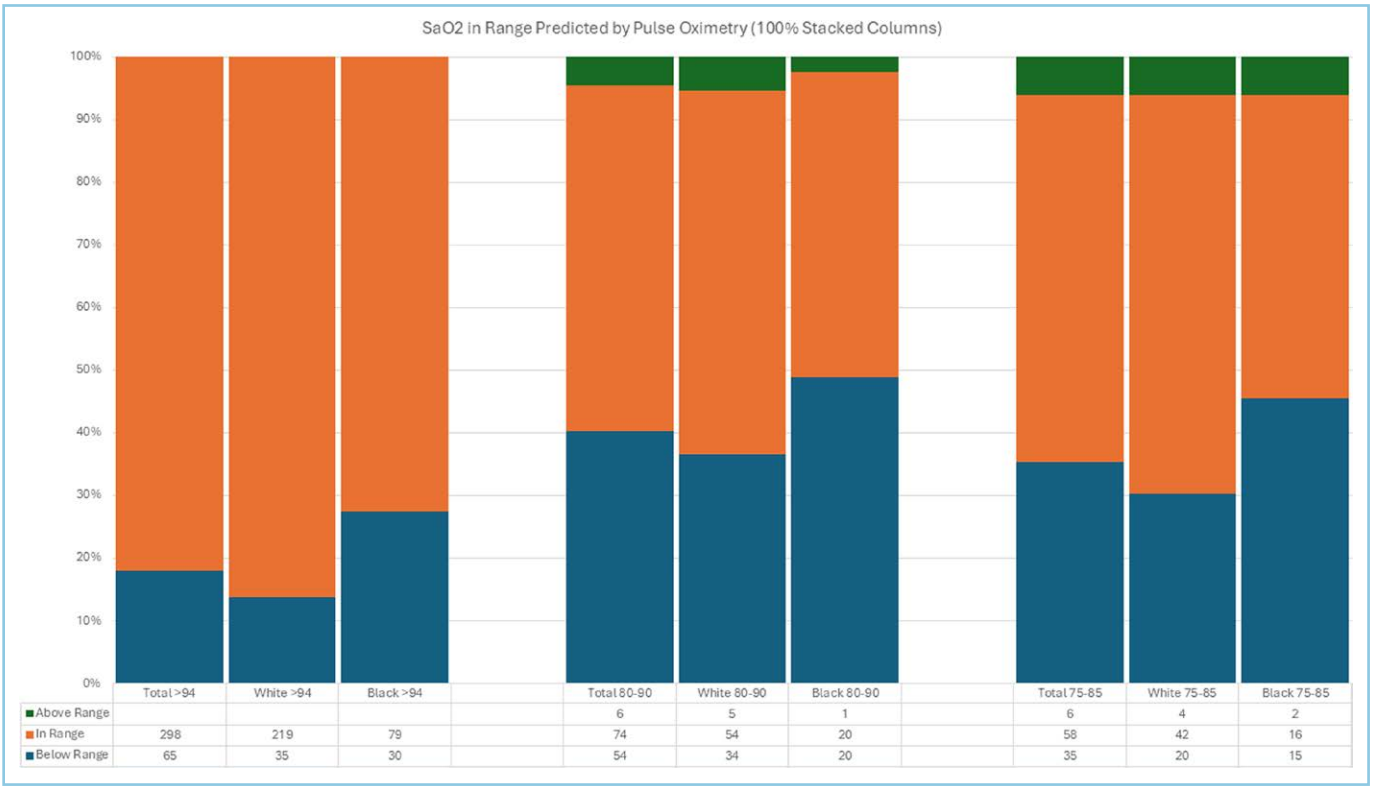


Figure 4. Stacked column graph showing the accuracy of Spo_2 to predict Sao_2 with certain clinically relevant ranges. Chi-square is $<$ 0.05 for patients with $Sao_2 > 94\%$ (p values for $>$ 94: 0.002; 80–90: 0.319; 75–85: 0.140).

oximetry data were recorded, we analyzed that which would typically correspond to a preductal position.

Race was retrospectively extracted from the EMR and, in this study, is used as an identifiable surrogate for skin pigmentation. Race is assigned in the EMR by the admitting clerk with the advice of the patient or their family. Race, as it pertains to this analysis, is a binary variable, and there is no way to retrospectively quantify the degree of skin pigmentation in our dataset. There is ongoing work under an National Institutes of Health grant to ascertain the effects of objectively measured skin pigmentation on the performance of pulse oximetry in children (14). Other factors may also influence the oximetric difference, such as bilirubin, free hemoglobin, diastolic runoff, perfusion status, and other physiologic variables that may be investigated in future work.

The race distribution in our dataset reflects the distribution in the State of Alabama, for which our center is the only in-state pediatric cardiac surgical program (15). This cohort may not be representative of populations at other centers.

CONCLUSIONS

The inaccuracy of pulse oximetry in predicting true arterial oxygen saturation, as defined by oximetric difference, increases with hypoxemia. This effect is likely greater for Black patients than for White patients in a cohort of pediatric patients admitted to a single pediatric cardiac ICU. There is ample space for further work to improve the performance of pulse oximetry on a patient-centered basis, including prospective work to identify and characterize technical bias related to skin pigmentation and improvement in pulse oximeter performance at physiologic extremes as are commonly encountered in the pediatric cardiac ICU.

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Funding was supported, in part, by the University of Alabama at Birmingham Department of Pediatric Cardiology funds.

The authors have disclosed that they do not have any potential conflicts of interest.

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