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Research Letter

Pulse Oximetry Error in Patients With Single-Ventricle Palliation

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Introduction

Pulse oximetry is a mainstay technology used to manage children with cyanotic congenital heart disease (CCHD). Using light absorption, the percentage of oxyhemoglobin (SpO_2) is calculated as a noninvasive estimate of arterial oxygen saturation (SaO_2). While managing children with CCHD, providers must ensure that the patient is within the acceptable range of hypoxemia because unexpectedly low SaO_2 indicates the need for intervention. In children with structurally normal hearts, the SpO_2 accuracy declines at lower SaO_2. The fact that pulse oximetry overestimates SaO_2 during hypoxia in patients with darker skin pigmentation has also been documented.[1] However, the degree of errors due to race and/or single-ventricle physiology in patients with CCHD has not been fully elucidated.[2-5] In this research letter, we used time-matched SpO_2-SaO_2 pairs collected during cardiac catheterization to investigate SpO_2 error as a function of SaO_2, self-reported race, and single-ventricle palliation.

Methods

We conducted a single-center, retrospective review of children with single-ventricle palliation undergoing cardiac catheterization. SpO_2 was measured using the IntelliVue X3 system (Philips), and SaO_2 was measured from arterial samples using the GEM Premier 4000 system (Werfen). Time-matched data pairs (recorded at a maximum of 60-second intervals) were extracted from the procedure log and race identifiers from the Society of Thoracic Surgeons and IMproving Pediatric and Adult Congenital Treatments databases. Self-identified African Americans (AAs) were compared with those who did not identify as AA. Patients were dichotomized to those with (Blalock-Thomas-Taussig shunt], patent ductus arteriosus stent, central shunt, and hybrid) and without diastolic runoff lesions.

Linear mixed-effect modeling was used to describe the relationship among the AA race, SaO_2, and SpO_2. The model included a random effect for the subjects and an interaction term to determine whether the AA race affects the relationship between SaO_2 and SpO_2. In the models, the SaO_2 was converted to a percentage <100% such that the intercept represented the expected SpO_2 when the SaO_2 was 100%. This study was approved by the Office of Research Integrity and Compliance.

Results

Four hundred thirty-nine SpO_2-SaO_2 pairs were extracted from 172 catheterizations performed on 130 patients (Figure 1D). Thirty patients (23%) representing 112 SpO_2-SaO_2 pairs (26%) were AAs. The median difference between SpO_2 and SaO_2 was +1% (IQR, −1% to +4%). The difference between SpO_2 and SaO_2 increased at lower SaO_2 ($B = -0.38$; $P < .001$). A significant interaction existed between the AA race and SaO_2 in the model of SpO_2 ($P < .001$), indicating that the relationship between SaO_2 and SpO_2 varied with the presence of the AA race. A significant interaction with SaO_2 also existed for age, sex, weight, body surface area, cardiac index, arterial blood pressure, pulse pressure, P_{CO2}, bicarbonate, the stage of palliation, and the presence of diastolic runoff, meaning that each of these factors affects the accuracy of SpO_2. The interaction between the AA race and SaO_2 in determining SpO_2 persisted even after controlling for these variables ($P < .001$). In the final model, which compared AA with non-AA subjects, the intercept was lower (91% vs 96%, respectively; $P < .001$) and the slope was less negative (−0.46 vs −0.75, respectively; $P < .001$), indicating that in AA patients, SpO_2 increasingly overestimated SaO_2 at lower SaO_2 (Figure 1A). For example, at an SaO_2 of 80%, the expected SpO_2 was 82% for AA patients vs 81% for non-AA patients, whereas at an SaO_2 of 60%, the expected SpO_2 was 73% for AA patients vs 66% for non-AA patients. Diastolic runoff was also correlated with SpO_2 values, which overestimated SaO_2 (Figure 1B), with the AA race and diastolic runoff representing additive risk factors (Figure 1C).

Discussion

Pulse oximetry significantly underestimates critical hypoxemia in self-identified AA patients and in the presence of runoff lesions, with

Abbreviations: AA, African American; CCHD, cyanotic congenital heart disease; SaO_2, arterial oxygen saturation; SpO_2, percentage of oxyhemoglobin.

Keywords: congenital heart disease; error; pulse oximetry; race; single ventricle; skin tone.

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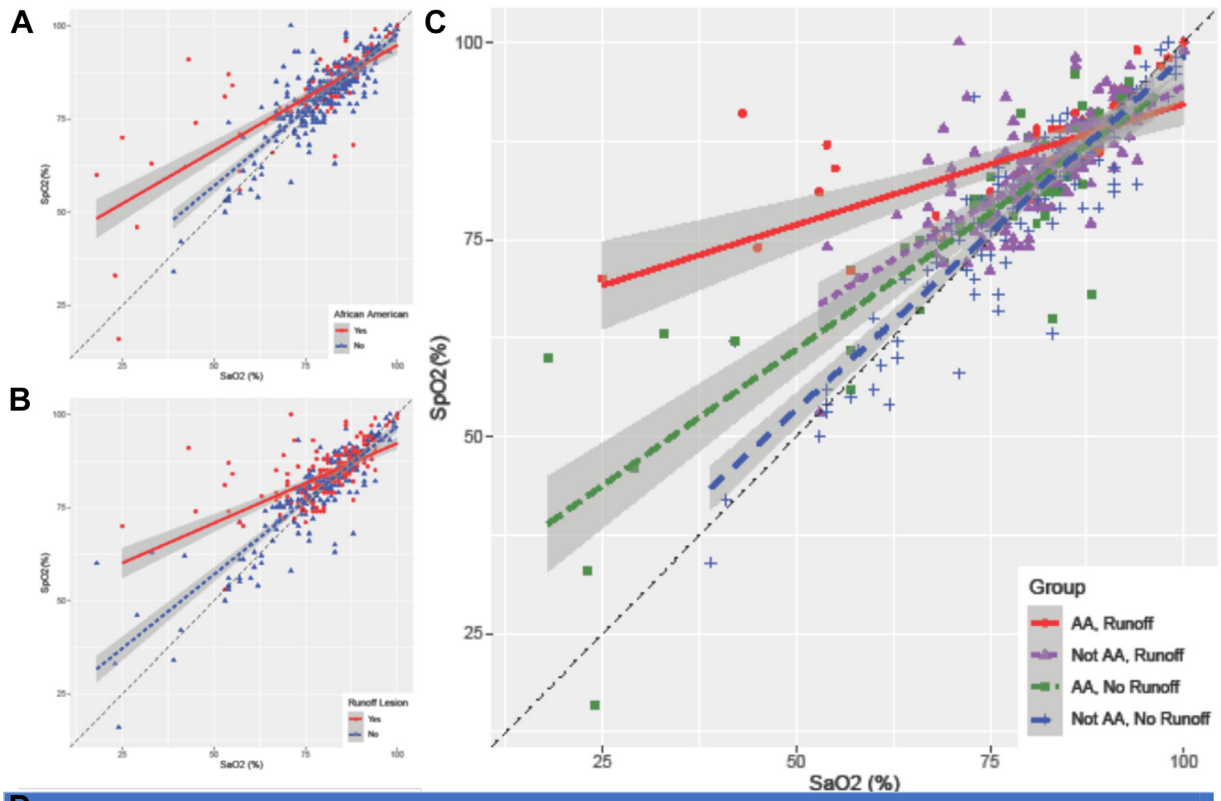

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	Catheterizations in non-AA patients	Catheterizations in AA patients	*P*
n (no. of catheterizations)	131	41	
No. of SaO_2-SpO_2 pairs per cath, mean ± SD	2.5 ± 1.5	2.7 ± 2.4	.46
Age (d), mean ± SD	190 ± 225	262 ± 375	.13
Male (%)	88 ± 67.2	11 ± 26.8	<.01
Weight (kg), mean ± SD	5.86 ± 2.55	6.00 ± 3.23	.78
BSA (m^2), mean ± SD	0.30 ± 0.09	0.31 ± 0.12	.67
Hgb (g/dL), mean ± SD	14.2 ± 2.0	14.6 ± 2.0	.27
Physiology category (%)			.43
Bidirectional Glenn	21 (16.0%)	8 (19.5%)	
Bilateral bidirectional Glenn	2 (1.5%)	0 (0.0%)	
BTTS	16 (12.2%)	2 (4.9%)	
Central shunt	3 (2.3%)	0 (0.0%)	
Hybrid	8 (6.1%)	2 (4.9%)	
PA band	15 (11.5%)	5 (12.2%)	
PDA stent	40 (30.5%)	9 (22.0%)	
Sano	15 (11.5%)	8 (19.5%)	
Unrepaired balanced	11 (8.4%)	7 (17.1%)	

Figure. 1. (**A**) Percentage of oxyhemoglobin (SpO_2) as a function of arterial oxygen saturation (SaO_2) and race. (**B**) SpO_2 as a function of SaO_2 and diastolic runoff lesions. (**C**) SpO_2 as a function of SaO_2, race, and diastolic runoff lesions. (**D**) Patient demographics. AA, African American; BSA, body surface area; BTTS, Blalock-Thomas-Taussig shunt; cath, catheterization; Hgb, hemoglobin; PA, pulmonary artery; PDA, patent ductus arteriosus; SaO_2, arterial oxygen saturation; SpO_2, percentage of oxyhemoglobin.

these errors being additive. Falsely elevated SpO_2 readings may cause clinicians to underdiagnose critical hypoxemia in AA patients with single-ventricle palliation and diastolic runoff, a population known to be at a high risk of mortality in the interstage period.

Without access to the manufacturer's proprietary algorithm for SpO_2, we can only speculate the reason for increased errors in the setting of runoff lesions. In principle, all pulse oximeters measure the ratio of pulsatile-to-nonpulsatile absorbance. These data were

collected from healthy volunteers, and an empiric algorithm was generated. We posit that in the setting of runoff lesions, the pulsatile component is significantly increased, thereby rendering the empiric formula less accurate. A next-generation device capable of correcting for the presence of widened pulse pressures could be invaluable.

The primary limitation of this study is that the correlation between skin tone and SpO_2 accuracy was not directly investigated. Rather, self-identified race was used as a proxy for skin tone. A single brand of pulse oximeter at a single institution was studied, and additional data are required to validate these results more broadly. Finally, potential factors, such as methemoglobinemia or carboxyhemoglobin, were not directly measured in this study but are known to affect the accuracy of pulse oximetry.

Conclusion

SpO_2 accuracy is negatively impacted by worsening hypoxemia, the AA race, and the presence of diastolic runoff, a novel finding of this study. The wide pulse pressure associated with runoff lesions was outside of the standard physiology based on which pulse oximetry was designed and validated and, thus, warrants further study. Ultimately, these data demonstrate that pulse oximetry can be falsely reassuring in our highest-risk patients with CCHD and present concerns that warrant further attention from device manufacturers and clinicians alike.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics statement

This study was approved by the Office of Research Integrity and Compliance (IRB 2021-4435).

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