

LETTERS TO THE EDITOR

Racial bias in accuracy of pulse oximetry and its impact on assessments of hypopnea and T90 in clinical studies

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Recently, there have been articles published regarding the racial bias in pulse oximetry measurement. Their findings may have implication in the measurements of hypopneas and Total sleep time spent with arterial oxygen saturation (SaO2) < 90% (T90). Black patients had nearly 3 times the frequency of occult hypoxemia that was not detected by pulse oximetry as White patients. In the multicenter cohort, the unadjusted analyses involving patients with an oxygen saturation of 92–96% on pulse oximetry showed an arterial blood gas oxygen saturation of less than 88% in 160 of 939 measurements in Black patients (17.0%) and in 546 of 8,795 measurements in White patients (6.2%).

Scoring of hypopneas use American Academy of Sleep Medicine criteria with 3% or 4% oxygen desaturation. If the pulse oximetry used in the polysomnography is not accurate in Black or Asian patients, conclusion for all those studies done in the last decade may need to be revisited. Several studies have documented Black men younger than 39 years and between 50 and 59 years have a higher apnea-hypopnea index compared to White men of the same ages after correcting for confounders and effect modifiers. Being a Black man younger than 40 years of age increased the apnea-hypopnea index by 3.21 breathing pauses per hour of sleep compared to a White man in the same age range with the same body mass index.

In The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, the chapter on digital and technical specifications states that desirable and minimal sampling rates for oximetry should be 25 Hz and 10 Hz, respectively. It does not state the minimal necessity of oximetry accuracy for polysomnography performance. Even most well done clinical studies do not give the accuracy of their device regarding oxygen saturation.

In another study, 3 of 4 oximeters (Masimo, Nellcor, and Philips) had root mean square error greater than 3% for oxygen saturation (SaO2) 70–100% during any motion compared to a root mean square error of 1.8% for the stationary control. This may have an impact in patients with multiple movements during their polysomnography.

Maybe it is time for the device specification to include accuracy regarding pulse oximetry, type of sensor used, and performance of the device in ranges between 80% and 100%. This may be critically important if we are going to use T90 as an

effective end point in clinical studies. Only then the conclusion of the studies may be acceptable for comparison in both clinical and research studies.

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All authors have seen and approved this manuscript. The author reports no conflicts of interest. This article reflects the views of the author and should not be construed to represent FDA's views or policies.