The effect of skin pigmentation on pulse oximeter accuracy

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Summary

This editorial is driven by recent reports highlighting potential inaccuracies of pulse oximeters in patients with different skin pigmentations. The authors summarise the pertinent literature and provide an overview of the potential clinical implications. The editorial closes by providing insights into how pulse oximetry could be improved to mitigate against such potential shortcomings.

Introduction

Pulse oximetry is a non-invasive optical technique used to assess arterial blood oxygen saturation (SpO_2) and is arguably one of the greatest advancements in patient monitoring in recent years. It entered clinical use in the 1980s, and since then has become the standard for oxygen saturation monitoring during anaesthesia, in the recovery room, and in intensive care units across the world [1]. It is attractive because of its simplicity, low cost, and ability to quickly detect hypoxaemia. Recently, pulse oximetry has been incorporated into wearable devices such as smartwatches. The widespread use of pulse oximetry in clinical and now consumer settings underlines the need to ensure it is as accurate and reliable as possible.

The accuracy of pulse oximeters has received renewed attention recently, fuelled by the need to identify hypoxaemia quickly and accurately during the progression of Covid-19. This is particularly true with patient-led pulse oximetry measurements in the home, which inform decisions as to whether to go to hospital. Several factors can impact the accuracy of pulse oximeters, including low perfusion, ambient light, motion artifact, nail polish, probe positioning, and irregular heart rhythms. However, it is the impact of skin pigmentation that has received greatest attention, with large-scale studies observing different levels of accuracy in people of different races and ethnicities. Recent research has found that pulse oximeters miss hypoxaemia more often in Black subjects than White subjects [2], and that missed hypoxaemia is associated with poorer outcomes in hospital patients [3]. In response, the UK Government has commissioned an independent review of the health impact of potential bias in medical devices [4], and the National

Institute for Health Research has issued a grant call for research into the 'diagnostic accuracy of pulse oximeters' [5].

In this editorial we summarise the pertinent literature relating to the accuracy of pulse oximeters in patients with different skin pigmentations and racial backgrounds. We then summarise the proposed routes to ensuring pulse oximetry provides accurate measurements for all.

Principles of pulse oximetry and its limitations

It is important to understand how pulse oximetry works to appreciate its limitations. Pulse oximeters estimate SpO_2 through the analysis of optical signals. Two or more optical pulse wave signals (photoplethysmograms (PPGs)), are created by illuminating a tissue bed (such as the finger) at different wavelengths of light and measuring the amount of light absorbed. Each signal exhibits a pulse wave: the amount of light received decreases and then increases with each heartbeat, as the tissue's blood volume increases in systole and then decreases in diastole. The PPGs are obtained simultaneously at different wavelengths of light (typically red (660 nm) and infrared (IR) (940 nm)), so that one is influenced more strongly by oxygenated blood, and the other is influenced more strongly by deoxygenated blood. SpO_2 can then be estimated by comparing the normalised amplitudes of the pulses in each signal: the amplitude of the pulsatile ('alternating current', AC) component is divided by the average amount of light received (the 'direct current', DC component). The ratio of their normalised amplitudes (R) is then calculated (equation 1), which relates to blood oxygenation. Finally, R is converted to SpO_2 using an empirical relationship (equation 2) which is learnt through calibration studies.

$$R = \frac{AC_{red}/DC_{red}}{AC_{IR}/DC_{IR}} \quad (1) \qquad \mathrm{SpO_2} = 110 - 25 \cdot \mathrm{R} \quad (2)$$

This provides insight into several of the limitations of pulse oximetry. Firstly, there is an implicit assumption that the relationship between the ratio of pulse amplitudes (R) and SpO_2 is similar for all subjects. Secondly, low perfusion can result in smaller variations in blood volume, and therefore smaller pulse amplitudes, reducing signal quality. Thirdly, movement and changes in ambient light levels can corrupt the signals, making the analysis unreliable. Pressing research questions include: (i) is a single empirical relationship suitable for all skin pigmentations; and (ii) is the amount of light received, and therefore the signal quality, influenced by skin pigmentation? With this background we now consider the literature on this topic and potential routes to improve pulse oximeters.

Literature on pulse oximetry and skin pigmentation

We identified 15 studies which compared the accuracy of pulse oximeters in groups of different race or skin pigmentation, using arterial blood oxygen saturation derived from blood gas measurements (SaO_2) as a reference [2 3 6 7 8 9 10 11 12 13 14 15 16 17 18]. The evidence has built since the late 1980s and has been enhanced by several important studies since 2020. The key findings are now discussed.

There is substantial evidence that at least some pulse oximeters are less accurate in Black patients (and those of darker skin pigmentation such as Asian patients) than White patients. The inaccuracies in Black patients mostly result in overestimating SaO_2, particularly at lower oxygen saturations (such as at $SaO_2 < 90\%$ [9]) . This is supported by emerging evidence from the UK [19]. However, the magnitudes of these inaccuracies are relatively small, such as a median difference in SaO_2 of 0.6% between Black and White patients with an SpO_2 of 90% (the threshold for making a diagnosis of hypoxaemia) [3]. There is also evidence that pulse oximeter signal quality can be lower in patients with darker skin pigmentation [7 10]. Only three studies did not find a difference in accuracy, all of which could have been underpowered to detect a difference (with 4, 14 and 34 subjects in the smallest group in these studies) [6 10 13].

The inaccuracies observed in Black patients, as well as other potential differences in their clinical condition and healthcare, may explain differences in clinical outcomes. Several studies have observed greater levels of hidden hypoxaemia in Black patients, where the true oxygen saturation was low enough to warrant clinical intervention, but this was hidden by erroneously high SpO_2 measurements [2 3 15]. In this context, the key consideration is the performance of pulse oximeters for identifying hypoxaemia (*i.e.,* performance at an SaO_2 of approximately 90%). It has been reported that performance for identifying hypoxaemia is significantly worse in Black patients than White patients: areas under the receiver-operating-characteristic curve of 0.84 (95% CI, 0.81-0.87) and 0.89 (0.87-0.91) respectively [2]. Furthermore, Black patients experience hidden hypoxaemia up to three times as frequently as White patients [2], and that disease state is associated with the occurrence of hidden hypoxaemia [3]. Evidence is now emerging that not only is hidden hypoxaemia more frequent in Black patients, but that it is also associated with poorer outcomes in hospital patients [3]. However, it is not yet clear to what extent other factors contribute to the observed differences in accuracy and outcomes, such as those relating to low perfusion and health disparities. For instance, White patients have been observed to be more likely to receive reference blood gas measurements than other patients [3].

There is also evidence that the performance of pulse oximeters varies between brands and between probe types [11 12 14]. For instance, the SaO_2 level below which significant inaccuracies occur varies between pulse oximeters [11 12]. Furthermore, data collated by the Open Oximetry Project (www.openoximetry.org) demonstrates the differing

performance of inexpensive pulse oximeters, many of which are used globally. For instance, some have an accuracy (root mean square error) of >4%, while others have an accuracy of <2% (e.g., JPD-500E by SantaMedical and Cms-50d by Contec Medical System, respectively).

There are several limitations to the current evidence. Firstly, most studies used race to stratify patients, rather than objective measurements of skin pigmentation. Secondly, recent large-scale retrospective studies cannot be used to quantify the accuracy of pulse oximetry as they used SpO_2 and SaO_2 measurements taken up to 5 or 10 minutes apart [2] [3]. Thirdly, research has mostly focused on adults, despite the importance of SpO_2 measurements in children and newborns (although [13] and [16] are notable exceptions). Fourthly, it is often not clear whether low quality SpO_2 measurements were excluded from analyses, which could be caused by low perfusion levels and associated with skin pigmentation. Finally, it is not clear how relevant older research is to current practice, as pulse oximeters have been refined since these studies. These limitations provide much motivation for further research.

Clinical implications

We now consider how the clinical use of pulse oximetry could be impacted by the evidence that the accuracy of pulse oximeters is influenced by skin pigmentation.

Pulse oximeters are widely used to identify hypoxaemia, such as when administering anaesthesia, when triaging patients in the Emergency Department, and during postoperative recovery. During the Covid-19 pandemic pulse oximeters have been used in the home to identify severe, unrecognised hypoxaemia, a common feature of acute Covid-19 and a predictor of worse outcomes [20]. There are three potential ways to address this in the short-term. Firstly, pulse oximeter models could be identified which are less susceptible to inaccuracies due to skin pigmentation. This requires prospective studies assessing multiple pulse oximeters in real-world settings [12]. Secondly, different threshold SpO_2 levels could be used to identify hypoxaemia according to the patient's skin pigmentation [3]. However, such thresholds would likely need to be specific to individual pulse oximeter models. Furthermore, selecting a threshold according to a patient's race could lead to inappropriate choice of thresholds in some patients whose skin pigmentation differs from the 'average' for their racial group [21]. Thirdly, in the context of Covid-19 it has been proposed that if pulse oximeters are inaccurate in "patients with darker skin", then they could be used to monitor changes in SpO_2 [22] to provide automatic administration of oxygen based on saturations thresholds [23] , or detect patients who may benefit from oxygen therapy [24] . However, research indicates that pulse oximetry does not necessarily track changes in true oxygen saturation

accurately [25]. Therefore, any steps taken in the short-term are unlikely to fully resolve the issue.

Pulse oximeters are also used to identify signs of disease and to inform diagnosis. Pulse oximetry is a fundamental component of polysomnography tests to diagnose sleep apnoea and assess its severity. In this case a pulse oximeter is used to identify desaturations indicative of partial reduction or complete cessation of breathing. Inaccuracies in pulse oximetry could therefore influence the accuracy of sleep apnoea diagnosis [26]. Pulse oximetry is also often used to screen newborn babies to identify low blood oxygen saturations associated with critical congenital heart defects [27]. The UK National Screening Committee has suggested that further research is required to support the use of pulse oximetry in this context [28], and it now appears important to assess the impact of skin pigmentation on its utility.

Engineering Perspective

One potential explanation for the inaccuracies observed in patients with darker skin is that the additional melanin in the skin could impact SpO_2 estimates independently of blood oxygen saturation [18]. As described earlier, the estimation of SpO_2 involves calculating the ratio of the normalised amplitudes of two pulse waves measured using red and infrared light. Each normalised amplitude is calculated by dividing the pulse wave amplitude by the amount of light transmitted through the tissue. The presence of melanin at higher concentrations, as found in patients with darker skin, and at different saturation values might have an effect in the amount of light transmitted at both wavelengths (mainly the red), which could result in an erroneous R value and hence an incorrect SpO_2 value. Therefore, it might not be reasonable to assume a single relationship relates R to SpO_2 for all skin pigmentations (equation 2). Perhaps pulse oximeters could use different relationships for different skin pigmentations, requiring either automatic recognition of skin pigmentation, or selection by the operator [11].

Conclusion

From the presented 15 studies, 80% have concluded that pulse oximeters are less accurate (overestimate true blood oxygen saturation) in subjects with darker skin. Awareness of this phenomenon has been heightened in the Covid-19 pandemic, where pulse oximeters have been used to identify hypoxaemia, contributing to treatment decisions. There is now evidence that hospital patients in whom hypoxaemia is not recognised by pulse oximetry experience worse outcomes. The impact of inaccuracies in pulse oximetry may also extend to other clinical scenarios, such as the diagnosis of sleep apnoea, and screening of new-born babies for congenital heart defects. Therefore, it is of utmost importance that this issue is addressed.

It has been proposed that the use of existing pulse oximeters could be adapted to account for the inaccuracies associated with skin pigmentation. However, we believe that the best solution is to refine the design of pulse oximeters to eliminate any bias associated with skin pigmentation.

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