Analysis
Pulse oximetry in primary care:
factors affecting accuracy and interpretation

INTRODUCTION

The COVID-19 pandemic saw a rapid increase in the use of pulse oximetry devices (PODs) in primary care to triage and monitor large numbers of patients and to help decide which patients required admission to hospital. In the UK, this included providing 300 000 PODs to patients as part of the 'virtual ward' programme and there have been calls to extend the use of remote monitoring to patients with other medical conditions.[1–3] However, the increased use of pulse oximetry has been accompanied by growing concern over the potential for PODs to produce inaccurate oxygen saturation (SpO_2) readings and the effect that this could have on critical decisions regarding the management of patients. This article discusses the factors that can lead to inaccurate SpO_2 readings and the implications that this could have for both GPs and patients.

THE ACCURACY OF PULSE OXIMETRY DEVICES (PODS)

In early 2021, both the Food and Drug Administration (FDA) and the Medicines and Healthcare products Agency (MHRA) issued safety communications regarding the potential for PODs to produce inaccurate readings.[4,5] The FDA's assessment of the situation is well balanced and worth noting:

'Pulse oximeters have limitations and a risk of inaccuracy under certain circumstances. In many cases, the level of inaccuracy may be small and not clinically meaningful; however, there is a risk that an inaccurate measurement may result in unrecognised low oxygen saturation levels. Therefore, it is important to understand the limitations of pulse oximetry and how accuracy is calculated and interpreted.'[4]

The accuracy of a POD is measured by comparing the SpO_2 reading to the arterial blood gas oxygen saturation (SaO_2) reading, across the range of SpO_2 values from 70–100%. Most manufacturers declare an accuracy of +/− 2–3% over that range. The typical accuracy (reported as Accuracy Root Mean Square or A_{rms}) of recently FDA-cleared pulse oximeters is +/− 2–3% of the SaO_2, while the MHRA states that the A_{rms} must be <4%.[4,5] However, the A_{rms} is a mean value, so for PODs that are FDA-cleared this generally means that, during testing, about 66% of SpO_2 values were +/− 2–3% of the

SaO_2 and about 95% were +/− 4–6%. This means that, if the SpO_2 reading was 90%, then the SaO_2 was generally between 86–94%. The level of inaccuracy increases with the degree of desaturation, such that accuracy is highest at SpO_2 readings of 90–100%, intermediate at 80–90%, and lowest below 80%. PODs not approved for clinical use have been shown to possess varying degrees of accuracy and, while some are capable of excluding hypoxaemia in patients, others demonstrate highly inaccurate readings.[6,7] It is also important to ensure that PODs are cleaned, maintained, and checked for accuracy regularly, as not doing so can lead to inaccurate readings being produced.[8]

SAMPLING ERRORS

PODs are tested under laboratory and not clinical conditions, so it is important to be aware of the extrinsic factors that can affect the accuracy of the SpO_2 reading, such as sampling errors. In pulse oximetry, sampling is performed non-invasively by measuring the absorption of light by oxygenated and deoxygenated haemoglobin (Hb) that is travelling through the finger in a pulsatile manner. Anything that blocks or interferes with the absorption of light has the potential to cause an inaccurate reading, including nail varnish, ink and henna tattoos, false nails, and dirt on or under nails, as well as contamination of the inner surfaces of the finger clip by blood or oily substances.[9–11] Non-alignment of the two arms of the finger clip probe, exposure to ambient light, and tissue thickness can also affect light absorption. There have been concerns for over 3 decades regarding the potential

for darker skin pigmentation to affect the accuracy of POD readings, and racial disparities in mortality and morbidity during the pandemic have raised the question as to whether this might be, in part, due to the difference in the performance of PODs in patients with darker skin pigmentation. Recent studies have indicated that there is a higher risk of occult hypoxaemia in patients with darker skin pigmentation, such that patients with SpO_2 readings of 92–100% could be significantly hypoxaemic with SaO_2 readings of <88%. This has led to the suggestion that the threshold for referring a patient to hospital for SaO_2 measurement should be lowered in patients with darker skin pigmentation, especially if the patient's symptoms, signs, or observations are indicating a greater degree of illness than the SpO_2 reading.[12,13] Since PODs sample Hb that is moving in a pulsatile manner, shivering, excessive finger movement, and venous pulsation can all cause inaccurate readings, as can peripheral shutdown in patients with cold peripheries due to the ambient temperature, Raynaud's disease, or beta-blockers, or where the finger is under-perfused. It may take up to 30 seconds for the software in a POD to produce an accurate reading, particularly when the signal strength is low.

INTERPRETING SpO_2 READINGS

There are a number of factors to consider when interpreting an SpO_2 reading in an individual patient. A low reading can be due to a wide variety of physiological and pathological conditions, so it is important to consider the position of the patient when

Box 1. Key points

- Pulse oximetry is used to estimate and monitor the oxygen level (oxygen saturation) in the arterial circulation.
- Pulse oximetry readings feature in many guidelines for the assessment and management of patients with respiratory symptoms and conditions.
- Clinicians should be aware of the factors that can adversely affect the accuracy and interpretation of oxygen saturation readings in their patients, especially when critical clinical decisions regarding the management of patients are based upon these readings.
- Clinicians should use pulse oximeters that have been approved for medical use and should ensure that these devices are cleaned, maintained, and checked for accuracy regularly.
- Clinicians should follow the guidelines that are available for performing pulse oximetry, in order to reduce the risk of sampling errors and the potential for these errors to result in incorrect clinical decisions being made.
- Oxygen saturation readings should be interpreted within the context of the patient, their history, and the other clinical assessment findings, along with an appreciation of the limitations of pulse oximetry in clinical practice.

the measurement is taken; the patient's symptom history, comorbidities, and medical history; and the other clinical assessment findings, when interpreting SpO$_2$ readings.[14] PODs are unable to detect some causes of hypoxaemia, or may underestimate the degree of hypoxaemia in these patients, and they do not provide information on the delivery and utilisation of O$_2$ at a cellular level. Hypoxaemia can be the result of a respiratory, cardiovascular, neurological, musculoskeletal, or haematological abnormality, so a careful and holistic assessment of the patient is required. For example, in a patient with COVID-19, a reading of 93% indicates that admission to hospital should be considered.[15] However, this reading would also be compatible with a secondary bacterial pneumonia, a pulmonary embolus, or a cardiac event with pulmonary oedema, all of which patients with COVID-19 are at increased risk of developing and for which immediate admission to hospital is indicated.[16] Similarly, a low reading in a patient with chronic respiratory disease could be longstanding, due to an exacerbation of that illness, or due to a new medical problem, such as a pneumonia, pulmonary oedema, a pneumothorax, a pleural effusion, or a pulmonary embolus. Other factors that can affect the accuracy or result in misinterpretation of a reading include abnormalities in the quantity and quality of the circulating Hb, so anaemia, haemoglobinopathies (including sickle cell disease), a high glycosylated Hb, and a high carbon monoxide (CO) level can all cause inaccurate readings, some of which cannot be detected by PODs.[17] For example, in heavy smokers, CO can lead to an overestimation of the SpO$_2$ by as much as 8%.[18]

DISCUSSION

Critical clinical decisions regarding the management of patients are often based on guidelines that feature a specific or narrow range of SpO$_2$ readings. However, both the FDA and the MHRA have issued advice that the SpO$_2$ reading should be regarded as an 'estimate' of the SaO$_2$ and that it may be more appropriate to use the trend in SpO$_2$ values over time when making clinical decisions, although evidence-based guidance on when and how trends should be used is currently lacking.[4,5] The implications for clinicians are as follows: First, clinicians should be aware of the limitations of pulse oximetry and of the factors that can cause inaccuracy and misinterpretation. Second, clinicians should use PODs that are certified for clinical use and ensure that PODs are cleaned, maintained, and checked for accuracy

regularly. Third, clinicians should follow the guidelines for taking SpO$_2$ readings, to reduce the risk of sampling errors. Finally, SpO$_2$ readings should be interpreted within the context of the patient, their history, and the other clinical assessment findings, as well as an appreciation of the limitations of pulse oximetry. These are basic rules that apply to the use of all medical devices. Pulse oximetry has proved to be an invaluable tool for the assessment and management of patients in primary care but it is not a perfect tool. Clinicians should be aware of the limitations of pulse oximetry, the factors that cause sampling errors, and the potential for misinterpretation when basing a critical clinical decision on an SpO$_2$ reading.

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