SWAT 183: Effect of skin tone on the diagnostic accuracy of pulse oximeters for measuring blood oxygen in patients in a randomised trial

Objective of this SWAT
To compare pulse oximeter-derived peripheral oxygen saturation (SpO2) values to co-oximeter-derived arterial oxygen saturation (SaO2) measurements from arterial blood gas samples, for a range of fingertip pulse oximeters used by the NHS COVID Oximetry@home scheme, in an ethnically diverse group of adults with a broad spectrum of skin tones admitted to UK intensive care units and enrolled in a randomised trial of oxygen therapy. We aim to determine the accuracy of these pulse oximeters across different skin tones and levels of arterial oxygenation.

Study area: Diagnostic accuracy study
Sample type:
Estimated funding level needed: Medium

Background
The commonest way to measure the level of oxygen in a patient is by using a pulse oximeter, which is a clip that is usually placed on a fingertip and provides a value where 96-100% is considered normal. Pulse oximeters are used the world over in virtually every medical setting. During the COVID-19 pandemic, an extremely high number of patients presented to hospitals with low oxygen levels and pulse oximeters were used to determine the severity of this lack of oxygen. If a patient's oxygen levels are very low, they are admitted to hospital for specialist treatment. Alternatively, if their level is only decreased a small amount, they may be sent home with a pulse oximeter to closely monitor their oxygen levels there. It is therefore imperative that pulse oximeters are accurate and reliable. An increasing number of studies have shown that for patients with darker (pigmented) skin, pulse oximeters may over-estimate their true oxygen level. This is because the pulse oximeter shines light through the fingertip and skin tone may affect the device's accuracy. Over-estimation of oxygen levels could under-estimate the severity of a patient's illness, lead to them receiving inadequate treatment and coming to unnecessary harm. The aim of this SWAT is to determine whether skin tone affects the accuracy of pulse oximeters and confirm whether they over-estimate the level of oxygen in people with darker skin.

This SWAT is a sub-study of the NIHR HTA funded UK-ROX trial, which is currently running in intensive care units (ICUs) across the UK (ISRCTN13384956). This is large-scale randomised trial evaluating conservative oxygen therapy (a target SpO2 of 88-92%) versus usual oxygen therapy in mechanically ventilated adult ICU patients in the UK. In order to increase the number of patients eligible for the diagnostic accuracy study, we will also seek approval to enrol mechanically ventilated adult patients who have been screened for, but not enrolled into UK-ROX.

24 ICUs enrolling patients into UK-ROX will be involved with this SWAT and enrolled participants will have their SpO2 values measured by two test pulse oximeters and compared to simultaneous SaO2 values from ABG samples analysed on a standard ICU arterial blood gas analyser for 24 hours. The differences between SpO2 and SaO2 will be compared in different skin tone groups and across a range of arterial oxygenation levels. Patient skin tone will be measured using a handheld spectrophotometer and based on the average of four readings.

Interventions and comparators
Intervention 1: SpO2 values measured by two brands of pulse oximeter randomly allocated for evaluation at each site involved in the SWAT.
Intervention 2: Simultaneous SaO2 values from ABG samples analysed on a standard ICU arterial blood gas analyser for 24 hours.

Index Type: Diagnostic accuracy study

Method for allocating to intervention or comparator
Non-Random

Outcome measures

Primary: The accuracy of pulse oximeter derived SpO2 measurement, validated against co-oximeter-derived SaO2 from arterial blood gas samples, compared in different skin tone groups and across a range of arterial oxygenation levels.
Secondary:

Analysis plans
The primary measure of skin tone will be the continuous ITA (individual typology angle) calculated from the average of the four spectrophotometer readings. The bias in SpO2 measurements (SpO2 minus paired SaO2) will be modelled as a function of SaO2 and ITA (including nonlinear and interaction terms as appropriate) using multilevel mixed effects models to account for clustering of multiple measurements within participants. Separate models will be fitted for each pulse oximeter evaluated. For ease of interpretation, patient characteristics and summary measures will be presented by six categories of skin tone (Very light, Light, Intermediate, Tan, Brown, Dark) based on standard cut-off values of ITA.

Possible problems in implementing this SWAT
Adequate recruitment of participants with a broad range of skin tones.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Intensive Care National Audit & Research Centre, Clinical Trials Unit
Contact email address: uk-rox@icnarc.org
Date of idea: 1/JAN/2022
Revisions made by: Intensive Care National Audit & Research Centre, Clinical Trials Unit
Date of revisions: 23/FEB/2022