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Original Article

Accuracy of the Masimo SET® LNCS neo peripheral pulse oximeter in cyanotic congenital heart disease

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Abstract *Introduction:* Non-invasive peripheral pulse oximeters are routinely used to measure oxyhaemoglobin saturation (SpO_2) in cyanotic congenital heart disease. These probes are calibrated in healthy adult volunteers between arterial saturations of ~75 and 100%, using the gold standard of co-oximetry on arterial blood samples. There are little data to attest their accuracy in cyanotic congenital heart disease. *Aims:* We aimed to assess the accuracy of a commonly used probe in children with cyanotic congenital heart disease. *Methods:* Children with cyanotic congenital heart disease admitted to the Paediatric Intensive Care Unit with an arterial line in situ were included to our study. Prospective simultaneous recordings of SpO_2, measured by the Masimo SET® LNCS Neo peripheral probe, and co-oximeter saturations (SaO_2) measured by arterial blood gas analysis were recorded. *Results:* A total of 527 paired measurements of SpO_2 and SaO_2 (using an ABL800 FLEX analyser) in 25 children were obtained. The mean bias of the pulse oximeter for all SaO_2 readings was $+4.7 \pm 13.8\%$. The wide standard deviation indicates poor precision. This mean bias increased to $+7.0 \pm 13.7\%$ at SaO_2 recordings <75%. The accuracy root mean square of the recordings was 3.30% across all saturation levels, and this increased to 4.98% at SaO_2 <75%. *Conclusions:* The performance of the Masimo SET® LNCS Neo pulse oximeter is poor when arterial oxyhaemoglobin saturations are below 75%. It tends to overestimate saturations in children with cyanotic congenital heart disease. This may have serious implications for clinical decisions.

Keywords: Pulse oximetry; cyanotic congenital heart disease; multi-wavelength co-oximetry; oxyhaemoglobin saturations; cyanosis; Bland–Altman

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Pulse oximetry is the standard non-invasive technique used to measure oxyhaemoglobin saturation (SpO_2). Its use is recommended as a basic standard of care by the Association of Anaesthetists of Great Britain & Ireland and the American Society of Anesthesiologists during anaesthesia and in critical care units.[1,2] These probes and associated software programmes are calibrated in healthy volunteers between arterial saturations of ~75 and 100%.[3] Saturations below this are derived by extrapolation, which may affect the accuracy. The USA Food and Drug Administration (FDA) 510(k) standards state that a pulse oximeter should have an accuracy root mean square (A_{rms}) of <3% when measuring SpO_2 between 70 and 100%.[4] The A_{rms} is a measure of overall accuracy and is calculated from the precision and bias. No standards exist for SpO_2 below 70%. The gold standard method for the measurement of oxyhaemoglobin saturation is multi-wavelength co-oximetry (SaO_2),[5] which requires arterial blood samples.

Children with cyanotic congenital heart disease commonly have oxyhaemoglobin saturations below or at the lower end of the calibration range for peripheral pulse oximeters. Despite the lack of data

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regarding the accuracy of conventional pulse oximeters in this context, measured values of SpO_2 are used to inform important clinical decisions.[2,6] They are also used to screen for cyanotic congenital heart disease in newborns.[7]

Recent data have questioned the accuracy of pulse oximetry in animal models,[8,9] adults,[10,11] and children.[6,12] Ross et al found that accuracy varied significantly in a cohort of children with hypoxaemia of any cause as a function of the SpO_2 range.[12] Inaccuracy of pulse oximetry has significant implications, particularly in patients with cyanotic congenital heart disease whose baseline saturations are low.

We assessed the accuracy of the Masimo SET® LNCS Neo peripheral pulse oximeter in a cohort of children with cyanotic congenital heart disease.

We hypothesised that the peripheral pulse oximeter would be inaccurate at extremes of hypoxia.

Methods

Setting

The study was performed in a 14-bed Paediatric Intensive Care Unit within the University Hospital Southampton NHS Foundation Trust in the United Kingdom.

Subjects

We included children in the Paediatric Intensive Care Unit with an echocardiographic diagnosis of cyanotic congenital heart disease and an arterial line in situ. We excluded children with duct-dependent lesions to avoid the influence of a patent duct on the pre-ductal and post-ductal saturations.

Study design

Paired measurements of SpO_2 (Masimo SET® LNCS peripheral pulse oximeter) and SaO_2 (ABL800 FLEX analyser) were recorded prospectively whenever an arterial sample was taken for blood gas analysis. The decision to obtain the arterial sample was at the discretion of the nursing and medical team caring for the child. The arterial sample was analysed immediately upon obtaining the sample with no time delay. The SpO_2 was recorded at the time the arterial sample was collected. The pulse oximeter had to have a stable recording for eight seconds after the removal of the arterial sample. This time period was specified to allow for the averaging time of the Masimo SET® LNCS peripheral pulse oximeter.[13] If the SpO_2 changed during sampling, the recordings were discarded. The saturation probe position was routinely changed to prevent underlying skin injury to the child, as per our departmental protocol.

Statistical analysis

Data were analysed using MedCalc v12.7.7. Bland–Altman plots for multiple measurements per subject were used to determine the agreement between the Masimo SET® LNCS neo peripheral pulse oximeter (Massimo Corporation 2013, California, USA) and multi-wavelength co-oximetry.[14] The bias of the Masimo SET® LNCS pulse oximeter was calculated from the difference between SpO_2 and SaO_2. Mean bias reflects the average difference between SpO_2 and SaO_2 across the entire data set. The precision was calculated from the standard deviation of the mean bias. The accuracy root mean square (A_{rms}) reflects both the bias and precision while correcting for the number of samples, and is used to describe the overall accuracy. Data were divided into two groups – above and below the lower calibration limit ($SaO_2 < 75\%$ and $SaO_2 \geqslant 75\%$[3]). Previous studies have all used SpO_2 to make this division, which seems counter-intuitive as SaO_2 is the gold standard.[5] In our analysis, we have selected to compare the difference between the two methods against the SaO_2 as the gold standard method, which is a recognised alternative approach to using the traditional Bland–Altman plots.[15]

Results

Sample size

We obtained 527 paired measurements of SpO_2 and SaO_2 in 25 children, with a median age of 112 days (range 1 day–4 years). The lowest recorded SpO_2 was 35%; the lowest recorded SaO_2 was 28.9%. The data points on the Bland–Altman plots display the agreement between the two values of SpO_2 and SaO_2; each marker represents one pair of observations.

Overall accuracy of the Masimo SET® LNCS Neo pulse oximeter

The mean bias of the Masimo SET® LNCS Neo pulse oximeter was $+4.7\% \pm 13.8\%$ (1.96 SD). The large standard deviation indicates poor precision. The A_{rms} was 3.3%. The Bland–Altman plot is displayed in Figure 1 and shows that the Masimo SET® LNCS Neo pulse oximeter both overestimates and underestimates oxyhaemoglobin saturations, but tends towards overestimation, sometimes by as much as 30%.

Accuracy of the Masimo SET® LNCS Neo pulse oximeter when SaO_2 was $\geqslant 75\%$

In 270 paired samples, the SaO_2 was $\geqslant 75\%$, and the mean bias was $+2.4 \pm 12.6\%$ (1.96 standard deviation) (Fig 2). The A_{rms} for SaO_2 readings $\geqslant 75\%$ was 1.7%.

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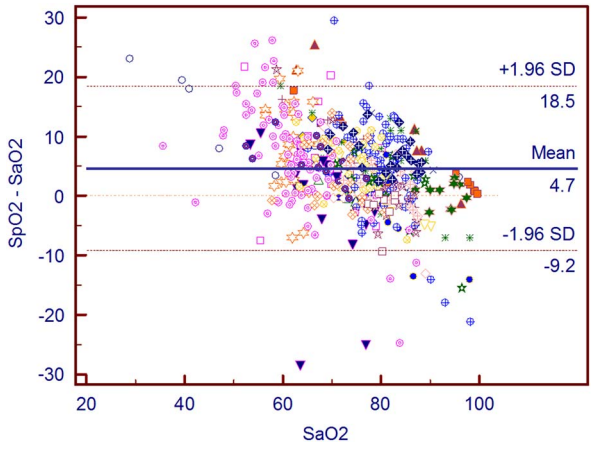

Figure 1.
Bland–Altman plot for all data points (n = 527).[14] *Each symbol represents one patient with multiple measurements per patient.*

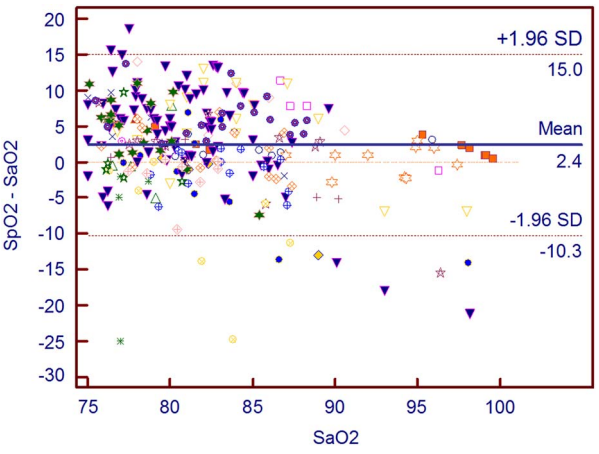

Figure 2.
Bland–Altman plot for co-oximeter SaO_2 recordings ⩾75% (n = 270).

Accuracy of the Masimo SET® LNCS Neo pulse oximeter when SaO_2 was <75%

In 257 paired samples, the SaO_2 was <75% and the mean bias was +7.0% ± 13.7% (1.96 standard deviation) (Fig 3). The A_{rms} for SaO_2 readings <75% was 5.0%.

Discussion

The accuracy of the Masimo SET® LNCS pulse oximeter diminished and the bias increased when SaO_2 was ⩽75% in this study. Agreement with the co-oximeter was poor when SaO_2 was <75%, with a tendency to overestimate oxyhaemoglobin saturation. This worrying observation is consistent with previously published data and leads us to question the use of these probes in children with cyanotic

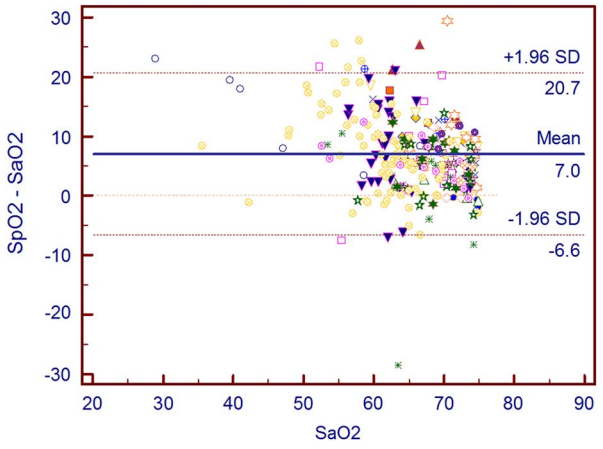

Figure 3.
Bland–Altman plot for co-oximeter SaO_2 recordings <75% (n = 257).

congenital heart disease.[6,8–12] Critical hypoxaemia may be undetected by these saturation probes and clinical decisions may be ill-informed. In our own unit, a critical incident occurred when clinicians were falsely reassured by SpO_2 values.

To the best of our knowledge, only a limited number of studies have investigated the accuracy of pulse oximetry in children with critical congenital heart disease, all of which showed that accuracy is impaired as SaO_2 falls.[6,12,16–19] SpO_2 both overestimates and underestimates SaO_2, with a tendency towards overestimation, which is consistent with the results of our study. Many studies have included children with non-cardiac causes of acute hypoxia, not the chronic hypoxia seen in children with critical congenital heart disease. A few studies have reported mean bias and precision, and only one other study[12] has reported the A_{rms}, which limits comparison between results. This study adds to the growing data highlighting concerns about the accuracy of pulse oximetry at the extremes of hypoxaemia, particularly in a cohort of children with critical congenital heart disease.

We acknowledge the limitations to our study. We included only a single probe for our data collection. The averaging time of peripheral pulse oximetry makes it difficult to guarantee simultaneous measurements of SpO_2 and SaO_2. We did not consider the influence of other factors that may have affected the measurement of SpO_2, such as haemoglobin, pH, arrhythmias, and low cardiac output states. A much larger data set is required to enable multivariate analysis to consider these issues.

In conclusion, when assessing the degree of hypoxia in children with cyanotic congenital heart disease, strong preference must be given to direct co-oximetry on arterial blood samples when available.

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Peripheral pulse oximetry should be used with extreme caution and with awareness of its limitations. Better algorithms are required for these probes before unqualified recommendations can be made for their use in the care of children with cyanotic congenital heart disease.

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Conflicts of Interest

None.

Ethical Standards

Following a discussion with the Local Research Ethics Committee, the requirement for formal ethical approval was waived.

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