Oxygen targeting in preterm infants using the Masimo SET Radical pulse oximeter

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ABSTRACT

Background A pretrial clinical improvement project for the BOOST-II UK trial of oxygen saturation targeting revealed an artefact affecting saturation profiles obtained from the Masimo Set Radical pulse oximeter.

Methods Saturation was recorded every 10 s for up to 2 weeks in 176 oxygen dependent preterm infants in 35 UK and Irish neonatal units between August 2006 and April 2009 using Masimo SET Radical pulse oximeters. Frequency distributions of % time at each saturation were plotted. An artefact affecting the saturation distribution was found to be attributable to the oximeter’s internal calibration algorithm. Revised software was installed and saturation distributions obtained were compared with four other current oximeters in paired studies.

Results There was a reduction in saturation values of 87–90%. Values above 87% were elevated by up to 2%, giving a relative excess of higher values. The software revision eliminated this, improving the distribution of saturation values. In paired comparisons with four current commercially available oximeters, Masimo oximeters with the revised software returned similar saturation distributions.

Conclusions A characteristic of the software algorithm reduces the frequency of saturations of 87–90% and increases the frequency of higher values returned by the Masimo SET Radical pulse oximeter. This effect, which remains within the recommended standards for accuracy, is removed by installing revised software (board firmware V4.8 or higher). Because this observation is likely to influence oxygen targeting, it should be considered in the analysis of the oxygen trial results to maximise their generalisability.

INTRODUCTION

Preterm infants often require supplemental oxygen for prolonged periods. There is considerable interest in the effect of oxygen therapy on morbidity and mortality in these infants.1–6 For more than 60 years there has been insufficient evidence to guide treatment and this is now the subject of an international group of randomised trials. The aim of these trials is to compare the outcomes of extremely preterm infants who have their pulse oximeter saturation (SpO2) maintained in either the range 85–89% or 91–95% until they reach 36 weeks corrected gestational age. The trials are using Masimo SET Radical pulse oximeters (Masimo, Irvine, California, USA). These oximeters were chosen because they were in widespread use when the trials were planned and are popular because of their ability to measure during patient motion and in circumstances of low perfusion.

METHODS

SpO2 data were gathered from 176 oxygen dependent preterm infants in 35 UK and Irish neonatal units between August 2006 and April 2009. Monitoring was performed for normal clinical indications using standard, unmodified Masimo SET Radical oximeters. Care was guided by these oximeters for a period of up to 2 weeks. During this time, the SpO2 data were recorded by the

detected by the oximeter sensor (figure 2) and use a calibration curve to convert these ratios into saturation values. In development, this conversion is validated against arterial blood samples measured by a CO-oximeter. The reduced frequency of SpO2 values of 87–90% is due to the calibration algorithm used by the oximeter. Inspection of the calibration curve in the area corresponding to SpO2 values of 87–90% shows a transition where the slope of the curve becomes steeper for a short section. The calibration curve has been generated by merging two separate curves and the change in slope is the

**RESULTS**

Pretrial audit data were obtained from 176 preterm infants; all were receiving supplemental oxygen at the time of study. Detailed clinical information was not gathered as the audit was not intended as a research study. Figure 1A shows the frequency histogram of saturation readings from one infant. The distribution has an artefactual appearance, with a large dip in the histogram due to a lower frequency of SpO2 readings in the range 87–90% than would be expected from the remainder of the distribution. It looked as if there were missing values. This appearance was identifiable in almost all histograms from individual infants. The area of apparently missing data always fell in the range 87–90%. The size of the area of missing values depended on the distribution of the remaining values. Where an SpO2 of 87–90% was in the middle of the patient’s distribution, the dip appeared large. Where the centre of the distribution was above a saturation of 90% so that values of 87–90% were in the tail, the dip appeared smaller. In a few cases with very high SpO2 values, the dip was not apparent as there were too few values in the range 87–90%. This is shown in figure 1B where histograms from five infants have been plotted, and in figure 1C where pooled data from all 176 audits have been combined, showing the overall effect on the saturation distribution of oxygen dependent preterm infants cared for using this oximeter.

**EXPLANATION**

We are grateful to Masimo Corporation for promptly identifying the explanation. Oximeters determine saturation by measuring the ratio of red to infrared waveform intensities detected by the oximeter sensor (figure 2) and use a calibration curve to convert these ratios into saturation values. In development, this conversion is validated against arterial blood samples measured by a CO-oximeter. The reduced frequency of SpO2 values of 87–90% is due to the calibration algorithm used by the oximeter. Inspection of the calibration curve in the area corresponding to SpO2 values of 87–90% shows a transition where the slope of the curve becomes steeper for a short section. The calibration curve has been generated by merging two separate curves and the change in slope is the
move from one curve to the other. Where the slope is steeper, the SpO\textsubscript{2} value returned increases more for each change in light ratio than would otherwise have been the case on either curve so that SpO\textsubscript{2} readings of 87–90\% become less frequent. From a SpO\textsubscript{2} of 87\% upwards, as the lower curve climbs to join the higher curve, SpO\textsubscript{2} reads progressively a little higher than would be the case with the lower curve. This leads to an artefactual elevation of SpO\textsubscript{2} readings that is maximal at a displayed value of 90\% and is around 1.6\% higher (effectively up to 2\% because oximeters display whole numbers). This elevation gradually reduces in size as SpO\textsubscript{2} increases further until it is no longer present at SpO\textsubscript{2} values above 96\%.

The manufacturers indicate that the upper curve was used to provide saturation readings consistent with the tendency of manufacturers at the time that the oximeter was originally produced to adjust saturations in the 90s upwards a little to obviate the effects of low levels of circulating variant haemoglobins. They added the lower curve, which is free of upward adjustment, in 2002 as newborn preterm infants were being targeted to lower saturations. The effect of this ‘dual’ curve is that the saturation values that are missing from the distribution in the region of 87–90\% have been shifted upwards by up to 2\% and there is a corresponding increase in the frequency of higher values.

Figure 3 shows SpO\textsubscript{2} data gathered from an oxygen dependent preterm baby who was being cared for using a Nellcor OxiMax N-600x oximeter (Covidien-Nellcor, Boulder, Colorado, USA). The baby also had an unmodified Masimo SET Radical pulse oximeter attached, and the two simultaneous saturation profiles show the reduced number of values of 87–90\% in the Masimo histogram and the higher number of SpO\textsubscript{2} readings of 91–96\% that were obtained with the Masimo oximeter.

Masimo Corporation supplied new software with a revised conversion algorithm (board firmware V4.8 or higher) that relied on a single calibration curve and this was installed into all BOOST-II UK trial oximeters in December 2008. Figure 3B shows a paired comparison of saturation readings obtained from an oxygen dependent preterm infant cared for using an oximeter with the new saturation algorithm and simultaneously monitored with a standard Masimo SET Radical oximeter with the original algorithm.

Figure 4 shows paired comparisons of SpO\textsubscript{2} values obtained from four infants whose clinical care was guided by one of four different current commercially available oximeters and who also had SpO\textsubscript{2} data gathered simultaneously with a Masimo SET Radical oximeter with the original software algorithm.

DISCUSSION
We have shown that when it is used to monitor preterm infants receiving supplemental oxygen, the Masimo SET Radical pulse oximeter returns a reduced number of values of 87–90\%. This is explained by the internal calibration algorithm, which changes in this region and adjusts SpO\textsubscript{2} values above 87\% upwards. A new software algorithm removed this artefact and returns a distribution of values that is similar to other current oximeters.

According to the product information, the oximeter is validated for accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70–100\% SpO\textsubscript{2} against a laboratory CO-oximeter. This variation equals ±1 SD, which encompasses 68\% of the population. The stated accuracy for neonates is ±3\%, so by this standard at least 68\% of the time the displayed SpO\textsubscript{2} reading should be within ±3\% of the simultaneous CO-oximeter value on an arterial blood sample. In this regard the original oximeter performs within all recommended accuracy standards.
It is possible that a slight artefactual elevation of saturation between 87% and 95% could mask some cases. It is becoming usual for bronchopulmonary dysplasia to be categorised by whether or not a saturation of 90% is maintained breathing air.12–14 An artefactual increase in \( \text{SpO}_2 \) from 89% to 91% would result in fewer infants being categorised as having bronchopulmonary dysplasia and might influence the duration of supplemental oxygen exposure.

In the neonatal oxygen trials, infants have been targeted using modified Masimo Radical SET oximeters to maintain saturations either in the range 85–89% or 91–95%.15 This artefact in the algorithm would be expected to reduce the number of saturation values in the target range in the group targeted to lower saturations. This might make this lower saturation target group harder to maintain within range, leading to more oxygen adjustments and greater variability in saturation, including time spent with high or low saturations.

When these observations were explained, Masimo Corporation provided the revised software, which eliminated the artefact, removing the deficit of values in the range 87–90%, and reducing the uplift in saturations. With assistance from Masimo the new software algorithm was installed into the oximeters of the BOOST-II UK trial in December 2008 and into the Australian and Canadian oxygen trial oximeters in early 2009, so that the final results of the international collaboration will be as generalisable as possible to current oximeters from Masimo and other manufacturers.

The SUPPORT trial was the first of the oxygen trials to complete recruitment. Outcomes to hospital discharge were published recently. There was a large and highly significant reduction in retinopathy of prematurity in the group who had their oxygen saturation targeted lower. The same group showed a slight excess of mortality, of borderline conventional statistical significance. The data monitoring committees of the ongoing trials in the UK, Australia and New Zealand and Canada reviewed their individual trial data in light of the SUPPORT trial results and independently recommended continuing recruitment to all three trials. The SUPPORT trial was completed before the oximeter modifications. Because the ongoing trials began evaluating an intervention that results in different saturation distributions, it is critically important to be identified and corrected. The authors thank Masimo Corporation for enabling the authors to take place and for promptly explaining the oximeter observations and providing the revised software.

In conclusion, we have shown that the algorithm used by one generation of the Masimo SET Radical oximeter returns data Should describe outcomes using either algorithm.

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**REFERENCES**


