Neonatal screening with pulse oximetry

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CHAPTER 8

Low signal quality pulse oximetry measurements in newborn infants are reliable for oxygen saturation but underestimate heart rate

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ABSTRACT

Aim: We assessed the influence of system messages (SyM) on oxygen saturation (SpO_2) and heart rate measurements from infants after birth to see if clinical decision-making changed if clinicians included SyM data.

Methods: Heart rate and SpO_2 of term infants were recorded using Masimo pulse oximeters. Differences in means and standard deviations (SD) were calculated. Permutation corrected the non-random distribution and inter-subject variation. SpO_2 and heart rate centile charts were computed with, and without SyM.

Results: Pulse oximetry measurements from 117 neonates resulted in 28,477 data points. SyMs occurred in 46% of measurements. Low signal quality accounted for 99.9% of SyMs. Mean SpO_2 with SyM was lower ($p<0.001$), while the SpO_2 SD was similar to data without SyMs. The SpO_2 centile charts were approximately 2% lower with SyMs included, but they were not more dispersed. Mean heart rate was lower ($p<0.001$) and more dispersed ($p<0.001$) when a SyM occurred. The heart rate centile charts were lower, with increased variability, when SyMs were included.

Conclusion: A SyM occurred frequently during pulse oximetry in term infants after birth. SpO_2 measurements with low signal quality proved reliable for monitoring an infant's clinical condition. However, heart rate could be underestimated by low signal quality measurements.

Key notes:

- This study assessed the influence of system messages (SyMs) on the oxygen saturation (SpO_2) and heart rate measurements of 117 term infants after birth to see if clinical decision-making changed if clinicians included data with SyMs.
- Low quality signals occurred often, indicating lower heart rate and SpO_2.
- There was little difference between measurements with, and without low-quality SpO_2 signals, but heart rate could be underestimated by low signal quality.

BACKGROUND

Current international neonatal resuscitation guidelines recommend the use of pulse oximetry (PO) to evaluate an infant's condition when resuscitation is indicated.[1-3] PO provides objective and accurate values of the saturation of peripheral oxygen (SpO_2) and heart rate in a continuous manner.[4, 5]

PO measurements of the SpO_2 and heart rate of infants needing no resuscitation have been used to develop reference ranges.[6-11] In these studies measurements with an alarm message or system message (SyM) on the pulse oximeter were excluded; in some studies almost half of all collected data were excluded.[7, 10] However, when evaluating infants at birth, very little distinction is made between the signals with and without SyM in daily clinical use. When resuscitation or stabilisation is needed, it can be difficult for clinicians to note the SyM and exclude these measurements while evaluating the infant's condition. This raises an important question: are measurements of heart rate and SpO_2 with a SyM obtained by pulse oximetry valid and useful for clinical decision-making. Furthermore, the feasibility of pulse oximeter measurements of heart rate and SpO_2 can be questioned, as almost half of the data on the pulse oximeter screen are considered to be of poor quality and should be excluded from clinical decision-making.

The Masimo Radical pulse oximeter provides a number of possible SyM messages: low signal

identification and quality (SIQ), low perfusion, sensor off and ambient light. A message of low perfusion appears when there are very low amplitude arterial pulsations. SIQ is a measure of confidence in the measurement by the oximeter's algorithm. The Masimo Radical oximeter determines signal quality as a range from zero to one and an SIQ of less than 0.3 is defined as low SIQ.[12, 13] While studies reporting PO measurements have excluded measurements with SyM from analysis, the manufacturer (Masimo) indicates that measurements with low perfusion values can be used. However, caution needs to be taken when the low SIQ message is shown, as the degree of confidence decreases.[6-11, 15] The manufacturer has also stated that measurements with low SIQ have a high probability of being correct. However, clinicians should proceed with caution and efforts should be undertaken to rule out sensor displacement, malpositioning, light interference, and combination of poor perfusion or motion artefacts for the cause of a measurement accompanied by SyM.[15] Therefore, the manufacturer has recommended that clinicians should exclude measurements with a low SIQ message when the oximeter is used for clinical research.[14]

A SyM is often obtained in PO measurements performed soon after birth; it is therefore useful for the clinician to know if all displayed values, including the measurements with SyMs, will influence the evaluation of the infant's condition using the current reference ranges. We investigated the differences between SpO_2 and heart rate measurements with, and without SyMs from a Masimo pulse oximeter to determine the validity of data obtained with a SyM. We also assessed whether the currently used reference charts would change significantly when SyM data were incorporated.

PATIENTS AND METHODS

For this study we used the PO recordings from a prospective observational study performed by 27 midwives in seven community midwifery practices in the Leiden region. Midwives supervised uncomplicated vaginal births at home, in birthing facilities, or in hospital.[16, 17] During the 10-month period from April 2011 to February 2012 the midwives used a Masimo Rad-8 hand held pulse oximeter (Masimo Corporation, Irvine, California), and obtained measurements directly after birth. The devices contained Signal Extraction Technology (SET, V.7.8.0.1) and were set to give a measurement every two seconds, with two-second averaging intervals and maximal sensitivity.

Midwives were provided with a timer, which was synchronised with the pulse oximeter, enabling time of birth and initiation of PO to be recorded accurately. Midwives placed a disposable sensor (Masimo Low Noise Cable Sensor (LNCS®) Newborn Sensor) around the infant's right hand. Preductal SpO_2 and heart rate were obtained for a minimum of ten consecutive minutes. Delayed cord clamping was standard care in these healthy term deliveries.

The study was approved by the Leiden Medical Ethics Committee in February 2011. As PO is non-invasive, the measurements were observational, and the pulse oximeter measurements were not used in clinical decision making by the midwives, only verbal parental consent was required as approved by the Ethics Committee. The consent was documented in the mother's medical record.

The PO data were downloaded using Trendcom software, which transfers rough data into an Excel spreadsheet (2003, Microsoft), with data points every two seconds including whether SyM occurred at that data point. All data, including those with SyM (low perfusion, sensor off, ambient light and low SIQ), were included for analysis.

Statistical analysis

We calculated the means and standard deviations (SD) for both heart rate and SpO_2 for signals with, and without SyMs and then compared them to assess whether there was a difference between signals with, and without SyMs. It is not possible to compare data with, and without a SyM at one time point within one patient, because only one of these alternatives is possible at each time point. Therefore, we computed the difference of the means and standard deviations between the data, with and without SyMs and added these differences across all time points. This resulted in four values for the systematic difference between data with, and without SyMs: for mean SpO_2, standard deviation of SpO_2, mean heart rate, and standard deviation of heart rate. To correct for the statistical dependence between measurements within a subject, and for the non-random patterns of SyMs, we performed permutation by randomly reassigning the observed patterns of SyMs between the subjects.[18] We repeated this reassignment 1,000 times, and each time we recomputed the means and standard deviations of heart rate and SpO_2. By reassigning the SpO_2 and heart rate values randomly, any association between subject and SpO_2 or heart rate was nullified. Finally, we compared the original, unpermuted values of the means and standard deviations of SpO_2 and heart rate to the corresponding 1,000 permuted values in order to obtain *p* values.

Data points were incorporated into LMSChartMaker Light Version 2.3 (Medical Research Council, UK; 2006) to produce centile charts for all measurements with and without SyM in order to assess whether reference ranges would change when data with SyM was included.[19]

Statistical significance was found if $p<0.05$. Calculations were performed using the statistical programme R.2.14.0 (R foundation for statistical computing, Austria; 2011).

RESULTS

Between April 2011 and February 2012 we recorded PO measurements from 117 neonates. A total of 28,477 measurements were collected, of which 12,970 (46%) were labelled with a SyM and 15,507 (54%) had no SyM. Of all the SyM data 12,963 measurements (99.9 %) were labelled as low SIQ and the remaining seven measurements were labelled as low perfusion. No other SyM occurred. None of the SyMs occurred in the first minute. In the following two to ten minutes SyMs occurred in 27%, 60%, 56%, 46%, 47%, 42%, 39%, 40% and 39% of the data respectively. In addition, we recorded the time from the birth of the infant until the umbilical cord was clamped in 45 infants, which showed that this occurred at a median of five minutes with an interquartile range of three to seven minutes.

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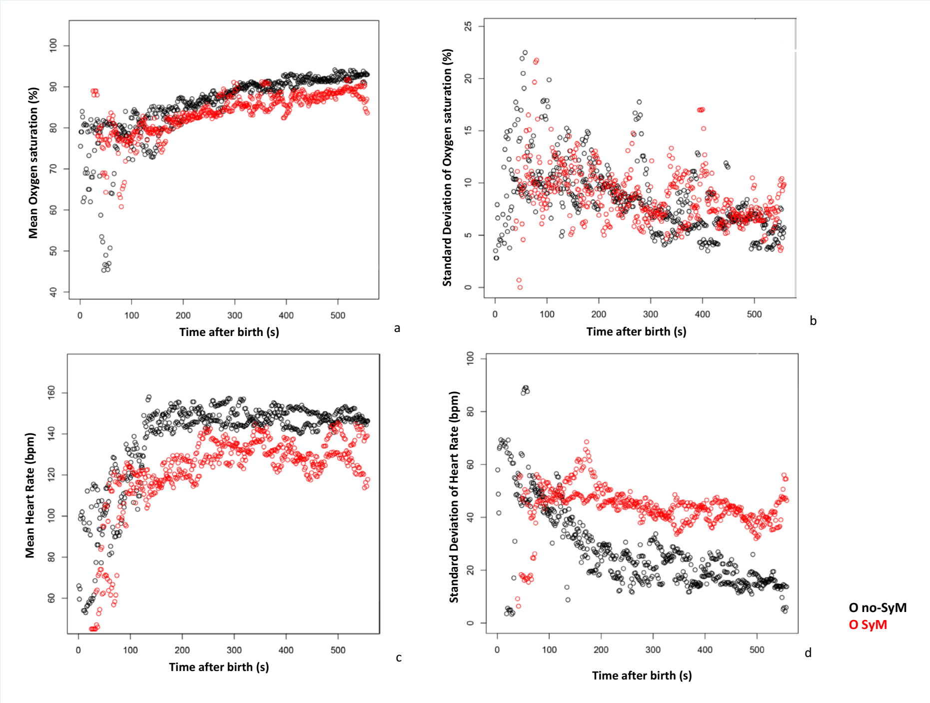
Oxygen saturation

The means and standard deviations for SpO_2 measurements from one to ten minutes after birth are shown in Figure 1A and 1B, respectively. The mean SpO_2 was significantly lower when the measurement was obtained with a SyM ($p<0.001$). There was no significant difference in the standard deviation for the SpO_2 measurements obtained with, and without SyMs ($p=0.30$).

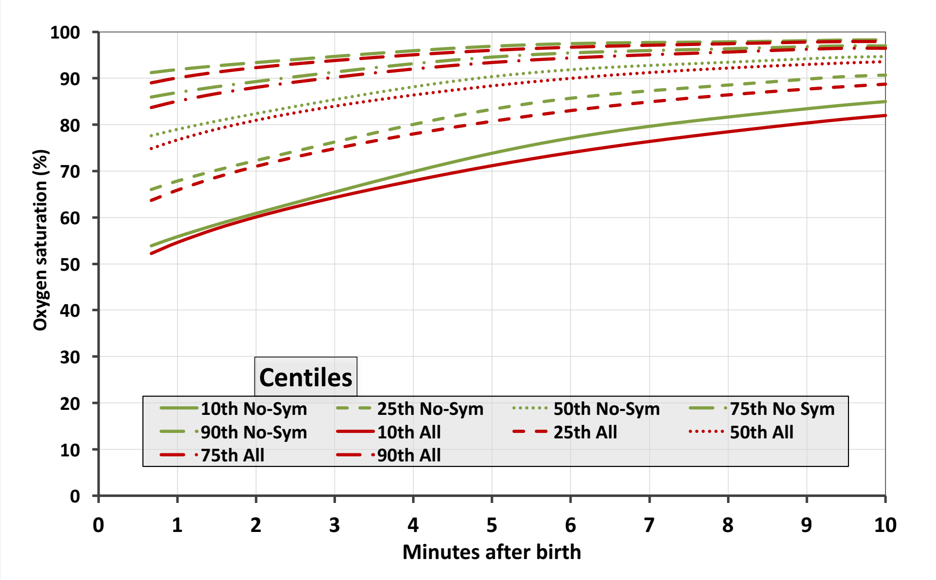
The centile charts from SpO_2 with, and without SyMs for one to ten minutes after birth are shown in Figure 2. On average, those measurements with SyMs were 2% lower than those with no SyM. The centiles were equally distributed and not more dispersed when SyM measurements were included.

Figure 1. Mean and standard deviation of oxygen saturation and heart rate per time point in seconds.



A) Mean SpO_2 in percentage per time point in seconds. B) SD of SpO_2 per time point in seconds. C) Mean heart rate in bpm per time point in seconds. D) SD of heart rate per time point in seconds. Every circle represents the mean or SD SpO_2 or HR at that certain time point. Black circles represent measurements obtained without SyM. Red circles represent measurements obtained with SyM.

Figure 2. Centile charts for oxygen saturation per minute for all signals and no-SyM signals.



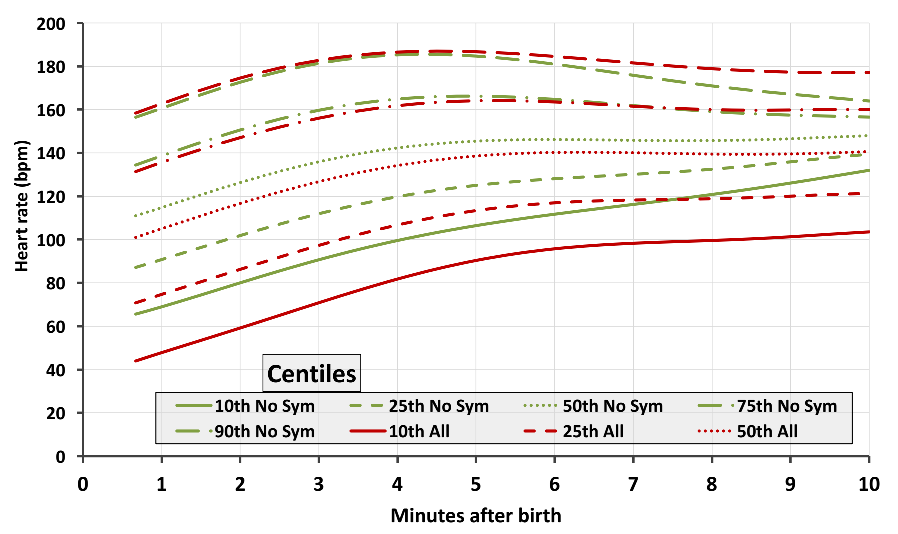
10th, 25th, 50th, 75th and 90th centile for SpO_2 are given for all signals in red and for no-SyM signals in green.

Heart Rate

The means and standard deviations of heart rate are shown in Figures 1C and 1D, respectively. The means and standard deviations of heart rate with SyMs was significantly lower than the heart rate obtained without SyM ($p<0.001$). The standard deviation of heart rate obtained with SyMs was significantly higher than the heart rate measurements obtained without SyMs ($p<0.001$).

The centile charts of heart rate without SyM signals and for all signals are shown in Figure 3. The 10th to 75th centiles of heart rate were lower when SyM data were included and the difference was highest in the lower centiles. The 90th centile was slightly higher in the first minutes after birth when we used all the data. In the last minutes, centiles of data without SyM signals converged, while centiles with all data diverged, showing more variability in heart rate when SyM data were included.

Figure 3. Centile charts for heart rate in beats per minute for all signals and no-SyM signals.



10th, 25th, 50th, 75th and 90th centile for HR are given for all signals in light red and for no-SyM signals in green.

DISCUSSION

This is the first study on healthy term infants not receiving interventions that compares PO SpO_2 and heart rate measurements with SyMs to those without SyMs. We observed that SyMs occurred in almost half of the measurements, which were mostly marked with low SIQ messages. This could make it difficult for a caregiver to interpret SpO_2 and heart rate measurements when using pulse oximetry for evaluating an infant after birth. It is useful to know if measurements obtained with SyMs are valid and usable for clinical decision making.

Mean SpO_2 was lower when obtained with SyMs compared to data obtained without SyMs. Although the difference in mean SpO_2 was small, it was statistically significant, probably due to the large number of measurements in this study. The standard deviation was not different when SpO_2 measurements with SyMs were compared to measurements without SyMs, indicating that there was no more variation in SpO_2 measurements for data with SyMs. The centiles produced for SpO_2 were also consistently lower, by around 2%, when SyM data were included, meaning that there was no more variability in SpO_2 when using all the data. Furthermore, this small absolute difference fell within the defined 2% margin of error of Masimo pulse oximetry and was, therefore, not clinically relevant.[20] The centiles were almost identical after inclusion of SyM data. For these reasons, clinical management will probably not be influenced by using all data, including measurements with SyMs. Therefore, it may be less important to note signal quality when evaluating SpO_2 at birth with PO.

We found that the mean heart rate with SyMs was significantly lower than the mean heart rate without SyMs. We have shown that there was a large range of heart rate measurements when signal quality was questionable. Additionally, when measurements with SyMs were included, the heart rate centiles were lower in the first minutes and became wider over time. In the lower heart rate range (10^{th} and 25^{th} centile) there was a potentially clinically significant difference in heart rate when SyM data were included. This means that clinicians should be aware of SyMs when interpreting heart rate with PO, especially when the heart rate is low. If a low SIQ message is not noted, it is possible that clinicians may underestimate an infant's heart rate.

SyM frequently occurred when using a pulse oximeter to measure heart rate and SpO_2 in newborns. The occurrence of SyMs in almost half of our data is comparable to previous studies in the same population.[6, 10] SyM predominantly indicated low SIQ (99.9%). Low perfusion occurred infrequently and no other messages occurred. It is possible that when other messages occur, for example in the Neonatal Intensive Care Unit, this might lead to other differences between measurement with, and without SyMs. For this reason, the difference observed in this study only refers to SyMs with low SIQ.

The high proportion of SyM signals might go unnoticed by clinicians when evaluating newborns. We hypothesise that clinicians look at the numbers, but may not take into account the quality of the signal. Consequently, they may not try to gain a better signal by re-siting the oximeter sensor. Moreover, when we consider the similarities in centile charts with all signals included and compare them to those with no SyM signals, it is also possible that the given values obtained with SyM met the normal values. Therefore, there might not have been a priority to improve the signal.

Previous studies using pulse oximetry excluded measurements obtained with SyMs for analysis, as has been recommended by the manufacturer.[6-11] However, very little data is available concerning the confidence level when there are measurements with low SIQ. Lang *et al.* analysed 10 neonatal files to assess whether low SIQ messages obtained with a Masimo Radical pulse oximeter reliably indicated compromised data integrity. This study showed that a low SIQ message demonstrated high sensitivity in detecting poor signal quality, without being displayed for an excessive amount of the monitoring time.[21] However, SpO_2 values were considered erroneous in the Lang *et al.* study if they deviated >10% from measurements obtained with other motion resistant pulse oximeters. Hence, findings from the Lang study must be interpreted with caution as they did not compare SpO_2 measurements against a gold standard. Masimo has stated that measurements with low SIQ have a high probability of being correct.[15] This might be true for SpO_2 where we observed little difference between data with, and without SyMs. In addition, the centile charts ranges (Figure 2) for SpO_2 were very similar for data with, and without SyMs, while we observed larger differences for heart rate.

In contrast to what we expected, few signals with SyMs occurred in the first minutes. It is possible that delayed umbilical cord clamping, with a median time of five minutes, influenced the quality of the signal. Therefore, the first heart rate and SpO_2 measurements were recorded before the cord was clamped.[16, 17] In a study of preterm lambs, Bhatt *et al.* demonstrated that ventilation before cord clamping stabilised the haemodynamic transition at birth by increasing pulmonary blood flow before the umbilical venous return was lost. This allows the supply of preload to the left ventricle to immediately switch from umbilical to pulmonary venous return when the cord is clamped.[22] No temporary decrease in left ventricular output and increase in systemic vascular resistance would occur in the first minutes. The pulse oximeter may find a signal more quickly before the cord is clamped. It is difficult to compare our findings with previous studies, as they do not report when SyMs occurred and they do not report the time of cord clamping.

It is impossible to obtain data with, and without SyMs for each infant at each time point. Therefore, we compared measurements of each subject against measurements from other infants obtained at the same time points. Inter-subject variation in heart rate and, or SpO_2, and variations in the amount of measurements with SysM is possible and could have influenced our findings. In addition, there was no random distribution in the occurrence of SyM. We performed a permutation test to nullify these potential effects of bias. Another limitation was the use of solely one model of oximeter. We therefore cannot be certain if our findings can be generalised to all pulse oximeters.

CONCLUSION

This study showed that SyMs occurred frequently during PO at birth using Masimo, predominantly displaying a low SIQ message. Mean SpO_2 and heart rate measurements obtained with low SIQ are lower than measurements without SyMs. The absolute difference in SpO_2 measurement with poor signal quality versus those with good signal quality was small, and they lay within the margin of error of Masimo pulse oximetry. The occurrence of low signal quality for SpO_2 measurements is, therefore, unlikely to affect clinical practice. However, the absolute difference in heart rate measurements with poor signal quality versus those with good signal quality was variable. Heart rate measurements with poor signal quality should be used with caution, as the possible underestimation of heart rate might affect clinical practice, especially in the lower range. The effect of signal quality on pulse oximetry should be further examined to provide more insight into the effect of signal quality on SpO_2 and heart rate measurements.

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