

Accuracy of Pulse Oximetry Measurement of Heart Rate of Newborn Infants in the Delivery Room

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Objective To determine the accuracy of heart rate obtained by pulse oximetry (HR_{PO}) relative to HR obtained by 3-lead electrocardiography (HR_{ECG}) in newborn infants in the delivery room.

Study design Immediately after birth, a preductal PO sensor and ECG leads were applied. PO and ECG monitor displays were recorded by a video camera. Two investigators reviewed the videos. Every two seconds, 1 of the investigators recorded HR_{PO} and indicators of signal quality from the oximeter while masked to ECG, whereas the other recorded HR_{ECG} and ECG signal quality while masked to PO. HR_{PO} and HR_{ECG} measurements were compared using Bland-Altman analysis.

Results We attended 92 deliveries; 37 infants were excluded due to equipment malfunction. The 55 infants studied had a mean (\pm standard deviation [SD]) gestational age of 35 (\pm 3.7) weeks, and birth weight 2399 (\pm 869) g. In total, we analyzed 5877 data pairs. The mean difference (\pm 2 SD) between HR_{ECG} and HR_{PO} was -2 (\pm 26) beats per minute (bpm) overall and -0.5 (\pm 16) bpm in those infants who received positive-pressure ventilation and/or cardiac massage. The sensitivity and specificity of PO for detecting $HR_{ECG} < 100$ bpm was 89% and 99%, respectively.

Conclusion PO provided an accurate display of newborn infants' HR in the delivery room, including those infants receiving advanced resuscitation. (*J Pediatr* 2008;152:756-60)

An infant's heart rate (HR) is used to assess the need for and response to resuscitation.¹ HR is determined by auscultating the precordium or palpating the umbilical cord. Intervention is recommended if the HR is < 100 beats per minute (bpm).^{2,3} Clinical assessment of HR in the delivery room is intermittent and often inaccurate.^{4,5} Pulse oximetry (PO), increasingly used in the delivery room,⁶ allows titration of oxygen concentrations delivered to infants receiving respiratory support.⁷ We have demonstrated that HR obtained by PO (HR_{PO}) in the neonatal intensive care setting is accurate compared with HR obtained from 3-lead electrocardiography (HR_{ECG}).⁸ ECG monitoring in the delivery room is difficult due to the infant's wet skin, is time-consuming,⁴ and may damage the skin of an extremely preterm infant. Conventional PO is unreliable in the delivery room, where excessive motion and low perfusion can lead to underestimation of true HR.⁹ Recently developed second-generation pulse oximeters have advanced processing algorithms to adjust for patient motion and poor perfusion states, thereby improving accuracy and precision.^{10,11} PO data are easily obtained from newborn infants in the delivery room,¹² but the accuracy of the HR_{PO} is unknown.

In the present study, we compared HR_{PO} determined by second-generation pulse oximetry with HR_{ECG} in newborn infants in the delivery room. Specifically, we sought to evaluate the precision and accuracy of PO across a wide range of HR_{ECG} readings and the sensitivity and specificity of PO in detecting $HR_{ECG} < 100$ bpm.

METHODS

Two investigators attended the deliveries of a convenience sample of newborn infants between July 2005 and August 2006. Use of the pulse oximeter in the delivery

bpm	Beats per minute	PO	Pulse oximetry
ECG	Electrocardiography	SD	Standard deviation
HR	Heart rate		

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Table. Delivery room interventions received by infants (not mutually exclusive)

Delivery room intervention	Gestational age, weeks			Total (%)
	28 to 31 (n = 12)	32 to 35 (n = 15)	≥36 (n = 28)	
None	4	8	24	36 (65)
Supplemental oxygen	8	8	3	19 (35)
Continuous positive airway pressure by mask	6	6	1	13 (24)
Positive-pressure ventilation by mask	6	6	0	12 (22)
Positive-pressure ventilation by endotracheal tube	3	2	0	5 (9)
Chest compressions	1	1	0	2 (4)

room has become a standard of care at our institution, and approval for the study as an audit of practice was obtained from the Royal Women's Hospital, Melbourne Research, and Human Research Ethics Committees. Verbal consent for video recording of the 2 monitors in the delivery room was obtained from the infant's parents before delivery.

Immediately after birth, the infant was placed on a resuscitation trolley, where a PO sensor (L-NOP Neo; Masimo Corp, Irvine, CA) was applied to the infant's right hand/wrist and then connected to a Masimo Radical signal-extraction pulse oximeter.^{12,13} The oximeter was set to acquire data with maximum sensitivity and a 2-second averaging interval.

Simultaneously, another study investigator applied 3 ECG chest leads (Puppydog; Kendall, Mansfield, MA), connected to an Escort II ECG monitor (MDE, Arleta, CA). The HR was based on a measure of the interval between R waves, averaged over 6 complexes. The oximeter and ECG monitor were placed side by side, and both screens were recorded by a video camera. PO and ECG measurements were available to the clinical team responsible for the infant.

Two investigators independently reviewed the videos. The videos were paused every 2 seconds to record data. The starting point for data collection was 10 seconds from the time at which both the HR_{PO} and HR_{ECG} data were displayed. One investigator recorded HR_{PO}, perfusion index (PI), and indicators of signal quality from the oximeter while masked to the ECG. The signal was deemed to be of "poor" quality if signal bars were absent at the bottom of the screen and/or the message "low-signal IQ" was displayed. The presence of bars and absence of message indicated a "good"-quality signal irrespective of the shape of the plethysmograph.¹⁴ The second investigator recorded the HR_{ECG} and signal quality while masked to the PO. The ECG trace was deemed to be of good quality if the QRS complexes were well formed and the rhythm strip was consistent with the HR_{ECG} displayed on the monitor. Data were recorded for a minimum of 3 minutes (90 data points). For an infant receiving advanced interventions (positive-pressure ventilation by face mask or greater), data collection continued until the infant was stabilized.

The relationship between HR_{PO} and HR_{ECG} was evaluated using Bland-Altman bias analysis; the difference between the measurements was plotted against their average. Two standard deviations around the mean difference repre-

sented the upper and lower limits of agreement.^{15,16} The sensitivity, specificity, positive predictive values, and negative predictive values of PO for detecting HR_{ECG} <100 bpm were calculated. The data were analyzed using intercooled Stata version 9.2 (StataCorp, College Station, TX).

RESULTS

We attended 92 deliveries and failed to make recordings at 37 of them, due to 20 ECG, 12 PO, and 5 video camera malfunctions. Consequently, we recorded and analyzed data from 55 infants who had a mean (\pm standard deviation [SD]) birth weight of 2399 g (\pm 876 g) and a mean gestational age of 35 weeks (\pm 3.7 weeks). The resuscitation administered to these infants is detailed in the Table. The time (median [interquartile range]) taken to acquire HR_{PO} was 68 seconds (60 to 118 seconds); that to acquire HR_{ECG} was 80 seconds (64 to 104 seconds); and that to the start of data collection was 118 seconds (90 to 155 seconds).

A total of 6475 HR_{ECG} and 6448 HR_{PO} data points were entered into the spreadsheet; the difference was due to transient loss of HR_{PO} and/or HR_{ECG}. All of the HR_{PO} data points were used to determine levels of agreement where the HR_{ECG} was deemed to be of good quality (n = 5877). The HR_{PO} and HR_{ECG} data for all infants were compared in a Bland-Altman plot (Figure 1A). The mean difference (HR_{PO} - HR_{ECG}) was -2 bpm, and the 95% limit of agreement (\pm 2 SD) was \pm 26 bpm. Figure 1B shows data from 2 active term infants in whom HR_{PO} significantly underestimated HR_{ECG}. When HR_{ECG} was compared with good-quality HR_{PO} (ie, presence of signal bars and absence of a "low-signal IQ" message; n = 5143), the mean difference (\pm 2 SD) was -1 bpm (\pm 20 bpm).

Figure 2 displays the level of agreement between HR_{PO} and HR_{ECG} for those infants receiving advanced resuscitation. The mean difference (2 SD) for the 5 infants who were intubated (Figure 2A) and the 2 infants who received external cardiac massage (Figure 2B) was 0.2 (\pm 16) and 0.8 (\pm 8) bpm, respectively.

Good-quality signals from both devices (n = 5143) are compared in Figure 3. A strong linear correlation ($r^2 = 0.8$) can be seen. Dividing this graph into 4 quadrants, above and below a HR of 100 bpm revealed a sensitivity of 89%, specificity of 99%, positive predictive value of 83%, and negative predictive value of 99% of PO to detect a HR_{ECG} <100 bpm. A HR_{ECG} <100 bpm was detected by PO 89% of the time.

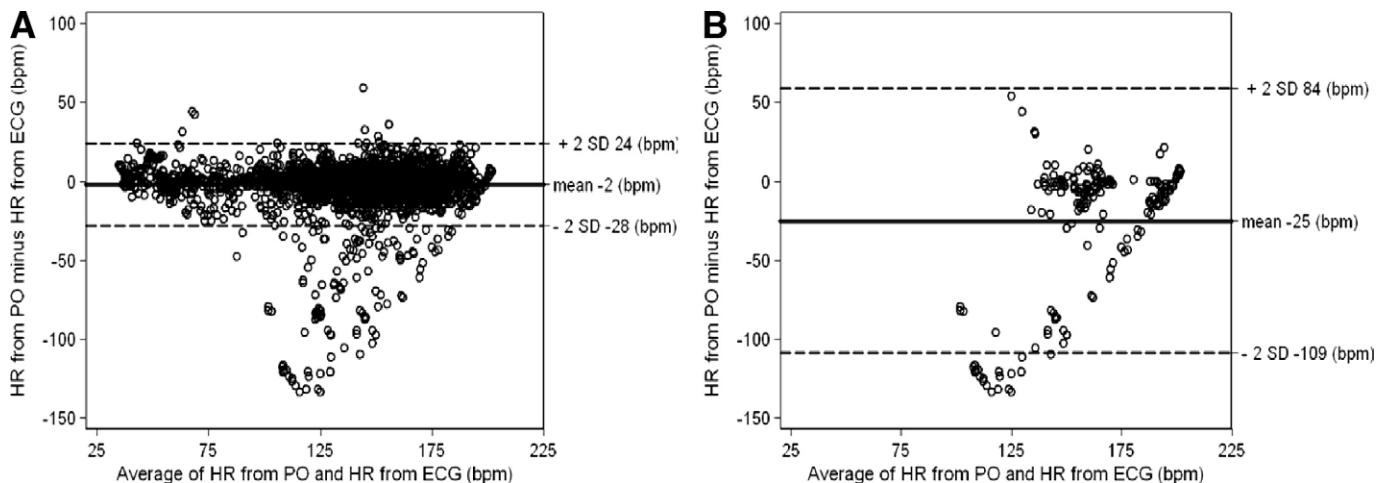


Figure 1. Bland-Altman plot showing the level of agreement between HR_{PO} and HR_{ECG} (when HR_{ECG} signals were deemed to be of good quality) in all infants (A) and in a subgroup of 2 infants in whom HR_{ECG} was consistently underestimated (B).

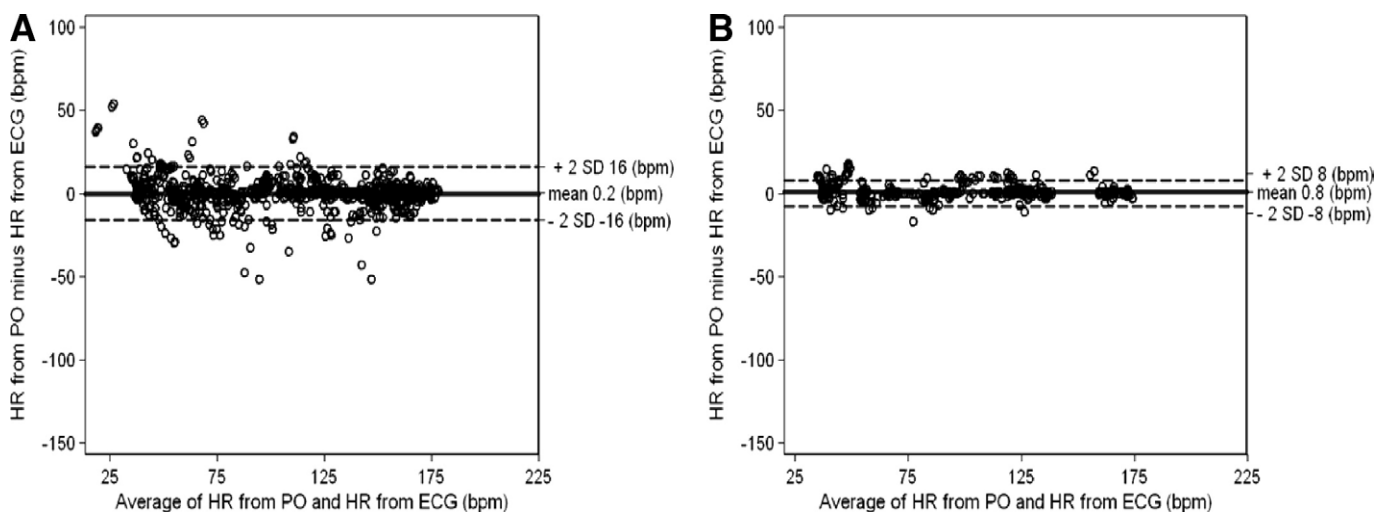


Figure 2. Bland-Altman plot showing the level of agreement between HR_{PO} and HR_{ECG} (when signals from both devices were deemed to be of good quality) based on maximum resuscitation intervention in the 5 infants who were intubated (A) and the 2 infants who received external cardiac massage (B).

There were 42 data points from 10 infants in which HR_{PO} was <100 bpm when HRECG was >100 bpm. One of these 10 infants contributed 16 data points (32 seconds); this infant received positive-pressure ventilation. The other 9 infants each contributed between 1 and 4 data points.

DISCUSSION

In this study, we evaluated the accuracy and precision of HR_{PO} in the delivery room using a new-generation pulse oximeter. Our results suggest that in the delivery room, HR_{PO} is accurate and on average within 2 bpm of HR_{ECG}. Overall, the 95% limit of agreement was wider than what we expected, at ± 26 bpm. However, in the infants who received the most intervention in our cohort, the level of agreement was ± 16 bpm. This compares with the pulse oximeter manufacturer's level of agreement of ± 10 bpm when tested on adult subjects with simulated motion.¹⁴

A weakness of our study is the high number of excluded infants (40%). The most common technical problem was failure to acquire HR_{ECG}. The video camera failed during 5 deliveries, due to lack of power or videotape. The pulse oximeter battery failed during 5 deliveries, and in 7 vigorous infants there was poor signal acquisition due to motion artefact. PO failed to acquire data in this setting in 12 of 92 infants (13%). Consequently, we advise caution in the application of this new technology; it may fail or, equally importantly, divert attention away from management of the infant in the stressful environment of the delivery room.

ECG and PO measure HR differently. There are differences in averaging intervals between the 2 devices, and thus it is possible that we have underestimated the true agreement between PO and ECG. With rapidly changing heart rates during neonatal transition, we observed that HR_{PO} may lag behind HR_{ECG} by a few seconds. Although clinically unim-

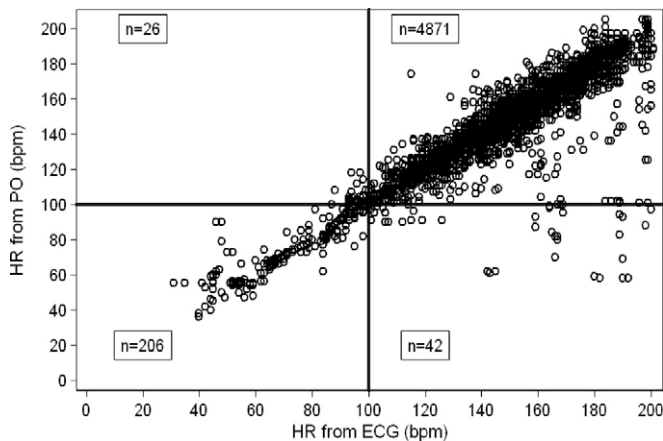


Figure 3. Scatterplot of paired data points when the signals from both devices were deemed to be of good quality. Each circle represents 1 data pair. The data are divided into 4 quadrants. HR_{ECG} (x axis) = 100 bpm; HR_{PO} (y axis) = 100 bpm.

portant, this lag would introduce differences between the 2 monitors in our data set, as demonstrated by the 26 readings in 5 infants in whom HR_{PO} remained >100 bpm while the HR_{ECG} had dropped to <100 bpm (Figure 3). One infant, of 31 weeks' gestation, contributed 12 data points in which the ranges of readings from the PO and ECG were 101 to 104 bpm and 96 to 99 bpm, respectively. These recordings are within the margin of error of the devices and are clinically unimportant.

The results on a small number of infants who required advanced resuscitation demonstrate the potential of this technology under these circumstances. Precision and accuracy were slightly improved in this situation (Figure 2). False-positive HR_{PO} readings (ie, where the PO incorrectly identifies an infant as having a low HR, potentially leading to inappropriate intervention) may be a concern. In our sample, 42 data points from 10 infants were noted in which HR_{PO} was <100 bpm and HR_{ECG} was >100 bpm (Figure 3). For all but 1 infant, these readings lasted between 2 and 8 seconds—insufficiently long, we believe, to alter management. In 1 infant who contributed 16 false-positive data points (32 seconds), PO may have led to interventions that were not indicated. However, overtreatment is probably less likely when using HR_{PO} than when using auscultation, which systematically underestimates HR by 17 bpm.⁴

PO may be inaccurate in vigorous infants. In our study, there were 2 infants in whom HR_{PO} underestimated HR_{ECG} by 100 to 130 bpm (Figure 1B). This may be due to poor apposition of the light-emitting diode and the photodetector after excessive limb movement or reduced perfusion as a result of fist-clenching. These infants were not excluded from the analysis because of our a priori commitment to record and use only PI, “low-signal IQ,” and the presence of signal bars as indicators of signal quality.

The International Committee on Resuscitation recommends 2 methods of evaluating HR: auscultation of the precordium and palpation of the umbilical cord.² Although

auscultation is superior to palpation, both methods are intermittent and inaccurate.^{4,5} We recognize that not every birthing area will have access to PO and that the stethoscope will remain the main instrument for assessing newborn infants worldwide. Based on our findings, we recommend using PO as an adjunct to careful clinical surveillance of infant HR, especially for very preterm infants who may need resuscitation. We have shown that PO can identify with high sensitivity and specificity those infants who require intervention based on current recommendations.

The availability and adoption of PO in the delivery room is increasing worldwide without extensive previous investigation. Kopotic and Lindner¹⁰ examined the feasibility and utility of the Masimo signal-extraction pulse oximeter in the delivery room to titrate the fraction of inspired oxygen to target saturations and assess the need for intervention using HR. In a feasibility study of early continuous positive airway pressure for extremely low birth weight infants in the delivery room, Finer et al used HR_{PO} to guide intervention in all but 1 of 47 infants who were intubated.¹⁷ Other studies have investigated the effects of endotracheal intubation on HR and peripheral oxygen saturation in the delivery room;¹⁸ none of these studies was designed to verify the accuracy of HR_{PO} , however. Our data demonstrate that HR_{PO} is of sufficient accuracy to be of use to clinicians and researchers alike.

The accuracy and precision of this technology have not yet been studied in extremely preterm infants; studies are needed in this patient group. Future studies also should address the question of whether PO used as an adjunct to clinical evaluation improves important patient outcomes in the delivery room.

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50 Years Ago in *The Journal of Pediatrics*

RECENT ADVANCES IN GENETICS IN RELATION TO PEDIATRICS

Fraser FC. *J Pediatr* 1958;52:734-57

Five years after Watson and Crick published their hypothesis on the structure of DNA,¹ Fraser opined about the trends in genetics, as well as their potential clinical applications. It is astounding how far the field has come in half a century. We now know that the normal chromosomal complement is 46, not 48, and that DNA is the carrier of genetic information. What is currently called the "central dogma" (DNA→RNA→protein) was a mere "modern concept" 50 years ago. The Human Genome Project, which completed the sequencing of the human genome in 2003, was not even a twinkle in a geneticist's eye in 1958.

From conceptual foundations to practical applications, the role of genetics in medicine has bloomed. Now, molecular testing is the gold standard for diagnosing a multitude of genetic conditions and is the preferred modality for assessing carrier status. State-coordinated newborn screening programs began in the 1960s with testing for phenylketonuria using a dried blood spot. Recently, many states have expanded their panels to screen for more than 40 conditions as a result of the introduction of tandem mass spectrometry into these programs, which has dramatically improved the ability to diagnose and treat inborn errors of metabolism before symptoms develop.

The first genetic counseling graduate program was established a decade after Fraser noted that "the demand for genetic counseling is growing and there is an increasing need for suitably trained counselors." There are now more than 2400 board-certified genetic counselors, and the need for these professionals continues to transcend multiple specialties, including pediatrics, adults, prenatal, cancer, cardiovascular, hematology, and neurology.

Most fascinating is how Fraser's words still ring true today: "Exciting things have been happening in genetics in the past few years, many of them directly or potentially relevant to the practice of medicine." This discipline has progressed greatly in the last 50 years, and there is still plenty of excitement to come. Medical Genetics is now a primary specialty with more than 1000 board-certified clinical geneticists, "personalized medicine" is on the horizon, and genetic testing is being marketed directly to consumers. The questions we now face are not just how to identify genes, but rather what can/should we do with this information. It was surely impossible for Fraser to predict that genetics would be so intimately involved in all aspects of health care, as we now know it today.

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