Pulse Oximeter Sensor Application During Neonatal Resuscitation: A Randomized Controlled Trial

OBJECTIVE: This study was done to compare 2 techniques of pulse oximeter sensor application during neonatal resuscitation for faster signal detection.

METHODS: Sensor to infant first (STIF) and then to oximeter was compared with sensor to oximeter first (STOF) and then to infant in ≥28 weeks gestations. The primary outcome was time from completion of sensor application to reliable signal, defined as stable display of heart rate and saturation. Time from birth to sensor application, time taken for sensor application, time from birth to reliable signal, and need to reapply sensor were secondary outcomes. An intention-to-treat analysis was done, and subgroup analysis was done for gestation and need for resuscitation.

RESULTS: One hundred fifty neonates were randomized with 75 to each technique. The median (IQR) time from sensor application to detection of reliable signal was longer in STIF group compared with STOF group (16 [15–17] vs. 10 [6–18] seconds; P = 0.001). Time taken for application of sensor was longer with STIF technique than with STOF technique (12 [10–16] vs. 11 [9–15] seconds; P = 0.04). Time from birth to reliable signal did not differ between the 2 methods (STIF: 61 [52–76] seconds; STOF: 58 [47–73] seconds [P = 0.09]). Time taken for signal acquisition was longer with STIF than with STOF in both subgroups.

CONCLUSIONS: In the delivery room setting, the STOF method recognized saturation and heart rate faster than the STIF method. The time from birth to reliable signal was similar with the 2 methods. Pediatrics 2014;133:476–482

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KEY WORDS
delivery room, neonate, pulse oximeter, sensor, signal acquisition

ABBREVIATIONS
NRP—Neonatal Resuscitation Program
STIF—sensor to the infant first
STOF—sensor to the oximeter first

Dr Louis conceptualized the study, performed pulse oximeter sensor application in all enrolled neonates, collected the data, and drafted the initial manuscript; Dr Sundaram conceptualized and designed the trial, designed the data collection tool, supervised the conduct of the trial, analyzed the data, and critically reviewed the manuscript; and Dr Kumar coordinated and supervised the planning, conduct, and analysis of the trial, and critically reviewed the manuscript. All authors approved the final manuscript as submitted.

This trial has been registered with the Clinical Trials Registry—India (CTRI/2013/05/003631).

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The Neonatal Resuscitation Program (NRP) guidelines advocate the use of pulse oximeters during resuscitation, especially when there is a need for providing positive pressure ventilation or supplemental oxygen.1 However, obtaining pulse oximeter signals quickly and reliably in the delivery room can be challenging due to various factors (eg, the effect of transitional circulation, low volume state, motion artifacts, vernix, skin edema, acrocyanosis), all of which could delay the signal acquisition process.2–5

The technique of pulse oximeter sensor application may also alter the time taken to display a reliable signal. This possibility was reflected in the study by O’Donnell et al6 who compared 3 different methods of sensor application in ICU infants in stable condition; they observed that the time taken to display accurate heart rate was the shortest when the sensor was applied first to the infant and then to the extension cable. Another small, nonrandomized study in a delivery room setting by the same group found that the sensor to the infant first (STIF) technique provided faster, as well as more, accurate readings.7 Based on these findings, the recent NRP guidelines recommend attaching the sensor first to the newly born infant and then to the extension cable of the oximeter (Level of Evidence Class IIb, Recommendation Level C).1 Both these studies had numerous methodologic drawbacks and were conducted in 2004 with previous-generation pulse oximeters. In the present study, we compared the 2 techniques of pulse oximeter sensor application in newborn infants immediately after birth in a randomized controlled trial by using a current-generation pulse oximeter to identify the better method for early and reliable signal acquisition.

METHODS

This trial was conducted in a level III neonatal unit of northern India over a 5-month period (January–May 2012). All pregnant women at \( \geq 28 \) weeks’ gestation and reporting to the delivery room in labor were potentially eligible for inclusion. Pregnancies with antenatally diagnosed major malformations of the lungs or airways, hydrops or skin edema, fetuses with congenital heart block, and stillbirths were excluded. One of the investigators assessed all mothers admitted to the delivery room for inclusion and exclusion criteria. If eligible, they were approached for participation in the study, and written informed consent was obtained from 1 of the parents. When mothers were in active labor and when delivery was imminent, they were randomly allocated to 1 of the 2 techniques of pulse oximeter sensor application. In cases of multiple pregnancies, mothers were randomized to study, but only the first of the multiples was enrolled. In situations in which 2 mothers were laboring concurrently, the mother who progressed earlier in labor was enrolled. Small for gestational age was defined when birth weight was \(< 10\)th percentile for that gestational age. Perinatal depression was defined as an Apgar score \(< 6\) at 5 minutes of life.

Randomization, Allocation Concealment, and Blinding

Deliveries were stratified based on gestational age into 3 groups: \( 28^{0}/7 \) to \( 30^{6}/7 \) weeks, \( 31^{0}/7 \) to \( 33^{6}/7 \) weeks, and \( \geq 34 \) weeks. Random allocation to 1 of the intervention arms was done within each stratum by using a Web-based random number sequence (www.randomization.com). A person who was not involved in the trial generated the allocation sequence, and the sequence was kept concealed until delivery. Block randomization with variable block sizes was done within each stratum to ensure equal numbers in each group. Allocation concealment was ensured by using opaque, tamper-proof, sealed envelopes. The envelope was opened only when the mother was shifted to the delivery table for an impending delivery. The first author enrolled the participants and designated the subjects to the allocated sequence. Blinding was not possible due to the nature of intervention.

The moment of cord clamping was considered as the time of birth for the purpose of the trial. Early cord clamping was the standard practice during the trial period. All trial infants were brought under a radiant warmer, and resuscitation was initiated according to NRP guidelines. The principal investigator dried the right hand of the infant and applied the pulse oximeter sensor as per sequence mandated by the allocation group.

Details of Interventions

Sensor to Infant First

In the STIF group, the pulse oximeter was kept switched on with the extension cable attached to the pulse oximeter. However, the patient sensor was not attached to the extension cable. Once the infant was placed on the radiant warmer, the sensor was applied first to the infant’s palm/wrist followed by attachment of the sensor to the extension cable. The attachment of the sensor was considered complete in this technique once the sensor was attached to the extension cable.

Sensor to Oximeter First

In the sensor to oximeter first (STOF) group, the pulse oximeter was kept switched on with the extension cable attached to the pulse oximeter and the patient sensor attached to the extension cable before delivery. Once the infant was placed on the radiant warmer, the sensor was applied to the infant’s palm/wrist, and this action was considered completion of sensor attachment in this technique.

A Masimo pulse oximeter Radical-7 model with a multisite low noise cabled sensor Y1 neonatal sensor was used for this trial (Masimo Corporation, Irvine, CA). The
monitor was set in the “MAX” mode for maximum sensitivity in low perfusion states with an averaging time set at 2 seconds. The sensor was applied and secured by using a Clean Shield multisite wraps (Masimo Corporation) along with 3M Durapore tape (3M, St Paul, MN) wherever required.

Outcomes

The primary outcome was the time taken (in seconds) from completion of application of the sensor to the appearance of the first reliable display of both oxygen saturation and heart rate on the pulse oximeter. Application of the sensor was considered complete in both techniques only if the sensor was attached to the oximeter through the extension cable, the oximeter was switched on, and the sensor was applied to the infant’s hand. Reliable display of heart rate and pulse saturation was defined as a stable display of heart rate and saturation without blinking. Primary outcome was recorded only in the absence of a “low signal quality” message on the pulse oximeter screen. Secondary outcomes measured included time from birth to start of sensor application (the point when the patient sensor touched the neonates’ hand was considered as the start of sensor application), time taken for sensor application, total time taken from birth to appearance of first reliable signal, proportion of infants in whom reliable data could not be recorded, and where the sensor had to be reapplied due to lack of signal.

At least 2 investigators attended all deliveries; 1 investigator was primarily responsible for placement of the sensor while the other investigator recorded different time intervals by using a stopwatch (model HS-80TW, Casio Inc, Tokyo, Japan) with an accuracy of 1 millisecond. The time measurements made on the stopwatch were immediately transferred to a data collection sheet between each enrollment.

The trial was approved by the institute ethics committee and was registered with the Clinical Trials Registry, India.

Sample Size

A previously published trial in a non-delivery room setting found that the mean ± SD time taken from sensor application to display of accurate heart rate was 23 ± 20 seconds when the sensor was attached to the pulse oximeter first and then to the infant (denoted as STOF in this study). To identify a 10-second decrease in the mean time taken from sensor application to reliable display of heart rate and pulse oxygen saturations by using an alternative technique in which the sensor would be attached to the neonate first and then to the oximeter (denoted as STIF in this study) with a 2-sided α error of 5% and power of 80%, a total sample size of 126 was required. Assuming a 20% loss of patient data due to lack of signal, a total of 150 neonates were recruited.

Statistical Analysis

Descriptive statistics were used for all baseline variables. The study arms were compared by using a $\chi^2$ test or Fisher’s exact test for categorical variables and Student’s $t$ test or its equivalent nonparametric test for continuous variables. A Kaplan-Meier curve was generated for time to reliable first signal between the 2 groups and was compared by using the log-rank test. An intention-to-treat analysis was conducted in this trial. $P$ values <.05 were considered significant. A subgroup analysis was conducted on the basis of gestational age and need for resuscitation. All statistical analysis was performed by using IBM-SPSS version 18 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

RESULTS

The flow of the study is shown in Fig 2. The baseline characteristics were similar between the 2 groups and were not statistically different (Table 1). The median (interquartile range) time from completion of application of the sensor to reliable signal acquisition (primary outcome) was significantly longer in the STIF group compared with the STOF group (16 [15–17] vs 10 [6–18] seconds; $P < .001$) (Table 2). Time taken for application was longer with STIF. Figure 3 depicts the comparison of time to reliable signal acquisition between the 2 groups by using a Kaplan-Meier graph. By the end of 10 seconds, ~58% neonates in the STOF group had a stable signal pattern compared with 5.4% in the STIF group. By the time it was 15 seconds’ postsensor application, ~75% in the STOF group had a stable rhythm versus 26% in the STIF group. After ~15 seconds, the neonates in the STIF group rapidly attained stable heart rate and pulse oxygen saturation measurements. However, a flatter portion appeared in both groups consisting of neonates in whom it took a prolonged period to obtain stable signal.

Other outcomes, including time from birth to sensor application, time from birth to appearance of reliable signal, and proportion of infants with reliable signal, were similar between the 2 groups. In all except 1 infant in the STIF group, a reliable signal could be recorded either after the first application or after reapplication of the sensor. A reliable signal could be obtained in all 75 infants in the STOF group, however. The need for reapplication of the sensor was more common with the STIF technique compared with the STOF technique (Table 2). Subgroup analysis of infants who required resuscitation showed results similar to that of the whole group (Table 3). The time taken for signal acquisition was uniformly longer in the STIF group than in the
STOF group across all 3 gestational age strata (Table 4).

**DISCUSSION**

In this open-label, randomized controlled trial, we observed that applying the sensor to the oximeter cable first (STOF) and then to the infant was significantly faster in detecting reliable saturation and heart rate signal compared with first applying the sensor to the infant (STIF) and then to the oximeter cable. These results are contrary to previously published reports and the subsequent NRP recommendations based on those reports.1,6,7 The time advantage of STOF over STIF was observed across all gestational ages ≥28 weeks as well as in infants who required resuscitation at birth. The re-application rate of the sensor was lower in the STOF group. The STOF arm also showed a trend toward a shorter time to reliable signal from birth. However, it was also observed that the confidence interval around the time to reliable signal from sensor application was narrower in the STIF group compared with the STOF group, suggesting that the STIF method may be more precise.

O’Donnell et al7 observed that using the STIF technique detected accurate heart rate more consistently and faster compared with 2 other techniques (1 of them being STOF) in their study conducted in a NICU setting. The same authors tested the utility of STIF in a delivery room setting in a non-experimental study design and reported results similar to their previous observations in a NICU setting.6 They hypothesized that when the oximeter is switched on with the sensor attached before applying it to the infant, the oximeter tries to average environmental “noise” and produces an artifact-generating signal. This action would delay the acquisition and display of data when the sensor is subsequently applied to the infant (as in STOF). However, this hypothesis does not consider the averaging time of a pulse oximeter. With shorter...
averaging times of 2 seconds, the signal would be replaced by a newer one averaged over the previous 2 seconds and thereby avoid such artifacts. In the STOF method, the oximeter would start detecting the infant’s pulse signal from the moment the sensor is applied to the infant’s hand, and by the time the sensor is completely applied (median of 12 seconds in STIF and 11 seconds in STOF from this study), the oximeter’s shorter averaging time window would have moved several windows ahead and would display a reliable signal. However, in the STIF method, when the sensor is applied to the infant, no signal is detected because the circuit is incomplete. After the sensor application to the infant is complete, it is connected to the oximeter extension cable and the oximeter starts picking up and averaging the signal, leading to a longer time to display a reliable signal.

On careful observation, one could see a clearly appreciable lag period of 15 seconds in the STIF group in attaining a stable heart rate and pulse oxygen saturation measurements followed by a rapid signal acquisition period compared with that of the STOF group. However, a flatter portion appeared in both groups representing neonates who took longer periods to obtain a stable signal. Although more neonates in the STOF group (n = 15) than in the STIF group (n = 4) had time to signal acquisition records ≥20 seconds (more deviant records ranged from 29–69 seconds), this difference was not statistically significant. This lag period observed with STIF and the clinical advantage of rapid signal acquisition after the lag period (Fig 3) would need further evaluation.

There are important methodologic differences between our study and previous reports. Although 1 of the previous studies in a delivery room setting was observational,6 the only other randomized controlled trial was conducted in NICU infants in stable...
TABLE 3 Comparison of Outcomes in Neonates Who Required Resuscitation (Subgroup Analysis)

<table>
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<th>Characteristic</th>
<th>Resuscitation (N = 48)</th>
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<tbody>
<tr>
<td></td>
<td>STIF (n = 23)</td>
<td>STOF (n = 25)</td>
</tr>
<tr>
<td>Time from completion of sensor application to reliable signal acquisition (primary outcome)</td>
<td>16 (15–17)</td>
<td>9 (5–14)</td>
</tr>
<tr>
<td>Time from birth to application of sensor</td>
<td>27 (24–31)</td>
<td>31 (26–40)</td>
</tr>
<tr>
<td>Time taken for application of sensor</td>
<td>12 (10–17)</td>
<td>9 (7–12)</td>
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<tr>
<td>Time from birth to appearance of a reliable signal</td>
<td>58 (53–71)</td>
<td>53 (45–59)</td>
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</table>

Data are presented as median (interquartile range). Time-related outcomes are expressed in seconds; continuous variables were compared by using the Mann-Whitney U test.

* Proportions with cell size <5 were compared by using Fisher’s exact test.

The latter study used heart rate from electrocardiogram tracings as the gold standard of a reliable pulse oximeter signal. However, an electrocardiogram is neither a practical nor a standard method in a delivery room setting. The observational study in the delivery room by the same authors reported a mere display of data as the primary end point but did not report how the data display was confirmed as reliable and accurate. The end points and their precise definitions are important because different end points would lead to different time measurements and a resultant lack of uniformity across studies. Because the pulse waveform or signal strength indicator may take a longer time to indicate a reliable signal, a stable display of data was considered the primary end point in the current study. In real life, in almost all scenarios, both the heart rate and oxygen saturation are displayed simultaneously. Hence, both parameters were taken together as the end point.

The delivery room setting offers a much different challenge compared with an infant in the NICU. The signal acquisition process has to occur in a relatively wet infant who is vigorous and actively moving his or her limbs and is still in the process of transitioning from fetal circulation. Current, new-generation pulse oximeters with shorter averaging times and the ability to detect arterial pulse signals by negating motion-related artifacts should perform better in such settings compared with older pulse oximeters. In this study, we used a new-generation pulse oximeter with short averaging time. These pulse oximeters have been shown to perform better than conventional pulse oximeters in the presence of motion artifact, low perfusion, high ambient light, or electrical interference from other equipments.

Our study has certain limitations. First, because we used a single brand pulse oximeter, our results may not be generalizable to other oximeters. However, we believe that any pulse oximeter with a similar short averaging time and the ability to detect signals during motion and low perfusion should perform in a similar fashion. Second, a single investigator applied the sensor in all neonates. In an open-label design, this action could have introduced an element of performance bias. Third, the validity of the definition of “reliable signal” was primarily based on logic and the manufacturer’s statement but was not actually tested.

**CONCLUSIONS**

Attachment of the pulse oximeter sensor to the oximeter first and then to the infant (STOF) in the delivery room setting measured reliable heart rate and oxygen saturation faster compared with the attachment of the sensor first to the infant and then to the oximeter (STIF) in infants of ≥28 weeks’ gestational age. The clinical implications of a faster detection of heart rate and pulse saturation, however, need to be studied further.

**ACKNOWLEDGMENTS**

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TABLE 4 Comparison of Outcomes in Neonates Stratified According to Gestational Age (Subgroup Analysis)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>28–30 Weeks</th>
<th>31–33 Weeks</th>
<th>≥34 Weeks</th>
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<tbody>
<tr>
<td></td>
<td>STIF (n = 23)</td>
<td>STOF (n = 26)</td>
<td>P</td>
</tr>
<tr>
<td>Time from completion of sensor application to reliable signal acquisition (primary outcome)</td>
<td>17 (15–18)</td>
<td>9 (6–13)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Time for sensor application</td>
<td>11 (9–14)</td>
<td>11 (8–13)</td>
<td>.4</td>
</tr>
<tr>
<td>Time from birth to application of sensor</td>
<td>27 (24–38)</td>
<td>34 (26–41)</td>
<td>.2</td>
</tr>
<tr>
<td>Time from birth to appearance of a reliable signal</td>
<td>55 (50–75)</td>
<td>55 (47–64)</td>
<td>.5</td>
</tr>
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</table>

Data are in seconds and are presented as median (interquartile range).
REFERENCES


A COMPUTER’S INTUITION: I was in Philadelphia last week and, as has happened so often in the past, my flight home was canceled. I was notified by an automated alert left on my cell phone. After almost 20 minutes on the phone listening and responding to several automated response systems, and hearing the same advertisements over and over again, I finally got to speak to an airline reservation specialist. She offered me a seat on the last flight out the next day, but not once did she comment on the difficulty of the situation or my frustration. Maybe next time I will have better luck with a computer.

As reported in The New York Times (Business: October 12, 2013), software developers have been working on programs that can detect human emotions. These programs do more than simply describe the meanings of the words spoken; they also attempt to match patterns and intonation with emotion and meaning. Humans are quite good at detecting sarcasm or when a person really does not mean it when he or she says “have a good day”, but until now, computers were not. While still in its infancy, the new software is remarkably good at discerning meaning. For example, a recording of one of Steve Jobs’ last interviews in which he discusses developing the touch screen for the iPad elicits the following comments from the computer program: “insistence, stubbornness, possibly childish egoism” and finishes with “sadness mixed with happiness; possibly nostalgia.”

I am pretty sure that most anyone could have detected the emotions in my voice when I was stranded in the airport last week, but maybe a sensitive computer would be a welcome change from the coolness of busy reservation specialists. While I am hesitant to recommend a computer program over a person for a conversation, at least the program might say “I understand or recognize your frustrations” and might not say “have a nice day” at the end of the phone call when it knows I will be in the airport for another 28 hours.

Noted by WVR, MD
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