

# Comparison of Latencies and Time to Stabilization of Pulse Oximeters at a Tertiary Health Care Facility

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## Abstract

**Introduction:** Fingertip pulse oximeters are commonly used as non-invasive modes of measuring oxygen saturation (SpO<sub>2</sub>) and heart rate (HR) in critical care units. In these cases, a shorter duration of time required obtaining the measurement and time to stabilization is crucial.

**Objective:** Our aim was to compare two new generation pulse oximeters with respect to latency in the first reading and time to stabilization of SpO<sub>2</sub> and HR.

**Materials and Methods:** This study was a prospective, comparative non-blinded, observational study of two fingertip pulse oximeters (Nonin Medical 9560 and CHOICEMMED MD300C1) in 20 in patients at Benedictine Health Center suffering from either one or more chronic diseases. SpO<sub>2</sub> and HR readings were collected at the time of first display, 30 s, 60 s and at the time of stabilization of the reading (no more than a 1% change in SpO<sub>2</sub>, <3 bpm change in HR). Statistical analysis was performed with SAS 9.2 software.

**Results:** A total of 20 subjects were monitored. The average time to first reading across all fingers was significantly longer with the CHOICEMMED device (10.3 ± 0.8 s) as compared to Nonin Medical (9.0 ± 0.8 s) pulse oximeter. The mean difference was 1.3 s (95% confidence interval (CI), (0.05, 2.61), *P* = 0.04). The average time to stabilization of SpO<sub>2</sub> across all fingers was also statistically significantly longer in the CHOICEMMED (27.4 ± 2.2 s) than Nonin Medical pulse oximeter (11.4 ± 2.0 s). The mean difference was 15.9 s (95% CI (12.57, 19.29), *P* < 0.0001).

**Conclusion:** The pulse oximeter (Model 9560) by Nonin Medical showed shorter latency for first reading and time to stabilization when compared to CHOICEMMED (MD300C1), which is a distinct advantage in emergency situations in acute patients. Further larger studies are needed to validate these findings in different clinical settings.

**Key words:** Comparison, Hypoxia, Latency, Oximeter, Saturation

## INTRODUCTION

Fingertip pulse oximeters are often used as a surrogate for measuring tissue oxygenation. They have proved to be useful tools in different hospital set-ups and even in challenging and adverse set-ups such as prehospital intubations and critical care in intensive care unit.<sup>1-3</sup> Use of fingertip pulse oximeters for efficient spot-check

assessment has increased with the greater availability of all-in-one portable devices.

In many clinical situations, the prompt availability of the result is as important as the value itself - for instance, in acute emergencies such as MI, anaphylactic shock, status asthmaticus or in ambulatory care when visits tend to be scheduled very frequently. In these cases, a shorter duration of time required to obtain the measurement is crucial.<sup>4-6</sup> While pulse oximeters perform well in routine conditions, factors such as severe hypoxia, artifacts, latency to first reading, and time to stabilization of readings adversely affect their utility in challenging patient conditions.<sup>6</sup>

Time to stabilization of the pulse oximeter and latency of readings is of critical importance in scenarios such as

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rapid-sequence intubation, pre-hospital intubation, and checking oxygenation status in sudden cardiac status, when any delay can be counterproductive to the patient's prognosis.<sup>7-12</sup> These parameters depend on sensitivity of signal acquisition of the pulse oximeter, signal averaging time of the oximeter, site of measurement, perfusion status, motion artefacts, arrhythmias, and hemoglobinopathies.<sup>8-10</sup>

Some studies have focused on this critical aspect. Macleod *et al.* showed that latency of response to hypoxia might be markedly different depending on hypothermia, site of measurement and hypoxic challenge.<sup>3</sup> Pulse oximeters use signal averaging time to obtain nonfluctuating measurement of oxygenation. Though signal averaging time in default mode is <10 s, it has been recommended that for finger pulse oximeters the time to stabilization and response to change in tissue oxygenation should be <30 s.<sup>3,4,7</sup> However, many such studies have been based in hypoxia laboratories and may not be reflective of their performance in clinical scenarios.

Aim of the present study was to compare the time to stabilization and time to first reading of two pulse oximeters used at a tertiary Hospital center in challenging patient conditions, and infer about their performance under the same.

## MATERIALS AND METHODS

### Design

This study was a prospective, non-randomized, non-controlled, observational study. The study was designed to include up to 20 subjects. Pulse oximetry was done on these patients in resting condition.

Subjects who met the inclusion/exclusion criteria were asked to participate as a volunteer in the study. Informed consent forms were made available to interested participants. A study representative from Benedictine Health Center of Minneapolis was available to answer any questions. When the study representative felt that the subject understood the purpose, procedures, benefits, risks, discomforts, and precautions of the study, the subject was asked if they wanted to participate in the study and if so, the subject was asked to sign the appropriate informed consent. Each subject received a copy of the signed informed consent.

Following receipt and documentation of the IRB-approved informed consent, subjects were considered enrolled in the study. The demographic and anthropometric questions were completed.

Subjects were seated in a private location and had a reference pulse oximeter placed on their right little finger

for the entire duration of the procedure. If other limitations or conditions existed, preventing placement on the little finger, the reference oximeter was placed on the left little finger or not placed on this subject and indicated on the chronic renal failures.

A video recorder was used to monitor the study. The recording window was limited to the subject's hands. The following test procedure was used for each oximetry system on each digit:

1. Apply the pulse oximetry system to the application site (e.g., finger)
2. Record the time to first displayed measurement
3. Record the time to stable measurement (no more than a 1% change in oxygen saturation (SpO<sub>2</sub>), <3 bpm change in pulse rate, or change in pulse strength)
4. Record the SpO<sub>2</sub> pulse rate, and pulse strength at first measurement, 30 s, 60 s, and stable measurement
5. Remove the sensor
6. Note special conditions during testing (e.g., imposed motion, patient motion, and device malfunctions) by marking the event in the collection system.

The order of placement and order of systems was randomized using a blocked randomization scheme with randomly sized blocks. The same application site was not used twice in a row. Each oximetry system was placed on each applicable location at least once during the testing.

For the extended stability and extend motion readings, the following procedure was performed:

1. Apply the test pulse oximetry system(s) to the application site (s) (e.g., finger)
2. Record the readings for a minimum of 10 min. Length of recording did not exceed 30 min.

### Devices

The devices used in this study included pulse oximeters manufactured by Nonin Medical Model 9560 and CHOICEMMED MD300Cl.

The pulse oximeters used in this study were indicated for use in measuring, displaying, and storing functional SpO<sub>2</sub> of arterial hemoglobin and pulse rate. Pulse oximetry sensors used in this study included fingertip pulse oximeters.

Instructions for installation and use of the devices, including any necessary storage and handling requirements, preparation for use, re-use requirements, pre-checks of safety and performance, and precautions to be taken after use were provided where appropriate.

### Statistical Calculation

Statistical analysis was performed with SAS 9.2 software (SAS Institute Inc., 2011. SAS System for Windows, Release

9.2. SAS Institute Inc., Cary, NC, USA) using generalized estimating equations to account for the correlation between multiple readings on the three fingers of the same subject.

## RESULTS

A total of 21 subjects were enrolled in this study between February 28, 2011 and September 22, 2011 at Benedictine Health Care Center. One patient withdrew consent prior to study participation, while remaining subjects participated. Subjects were enrolled from both white and non-white races. Subjects weighed an average 86.36 kg and were 172.5 cm tall. The demographic features are described in Table 1.

### Characteristics of Pulse Oximeters

Each of the subjects at Benedictine Health Center underwent simultaneous placement of a Nonin Medical Model 9560 and CHOICEMMED MD300Cl on the index, middle and ring fingers. One device was placed on the particular finger (index, middle, or ring) on the left hand, and the other device was placed on the same finger of the contralateral hand. The order of the placement was assigned using a randomizations scheme such that no finger had a sensor placed twice in a row.

With each placement, data were collected by visual inspection of the oximeters. These data included SpO<sub>2</sub> and heart rate (HR) at first reading, 30 s, 60 s and stabilization. Time to stabilization and time to first reading were also recorded.

The average time to first reading across all fingers was significantly longer with the CHOICEMMED device

(10.3 ± 0.8 s, mean ± standard error) as compared to Nonin Medical (9.0 ± 0.8 s, mean ± standard error) pulse oximeter. The mean difference was 1.3 s (95% confidence interval (CI), (0.05, 2.61), *P* = 0.04). (Figure 1) The average time to stabilization of SpO<sub>2</sub> across all fingers was also statistically significantly longer in the CHOICEMMED (27.4 ± 2.2 s, mean ± standard error) pulse oximeter than Nonin Medical pulse oximeter (11.4 ± 2.0 s, mean ± standard error). The mean difference was 15.9 s (95% CI (12.57, 19.29), *P* < 0.0001). (Figure 2) There was no significant difference between time of first reading for HR (*P* = 0.09) and HR at stabilization (*P* = 0.37) between the two oximeters.

### Study Flow

No follow-up was predicated or performed for this study. No adverse events were reported in this study. There were three protocol deviations. All three were deviations with respect to randomization order.

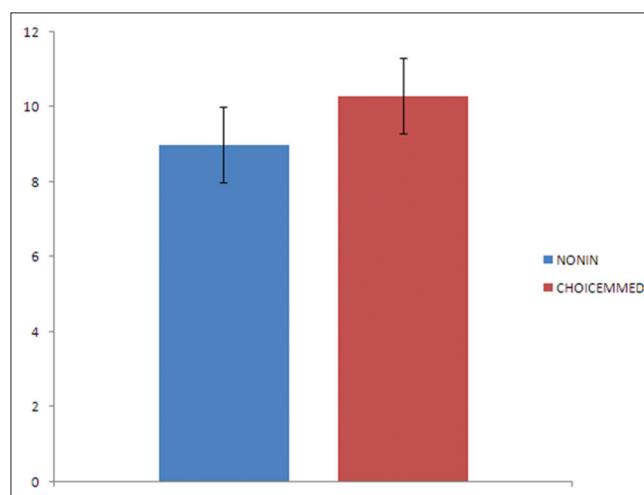


Figure 1: Comparative representation of time to first reading in both pulse oximeters in seconds

**Table 1: Demographic variables of participants of the study**

Characteristics	Benedictine Health (n=20 subjects)
Age	62±11.6
Gender (%)	
Male	14/20 (70)
Female	6/20 (30)
Race	
American Indian	1/20
Asian	0/20
Black	4/20
Pacific	0/20
White	15/20
Skin color	
Very light	4/20
Light	7/20
Intermediate light	5/20
Dark	4/20
Height (cm)	172.5±12.5
Weight (kg)	86.36±21.1

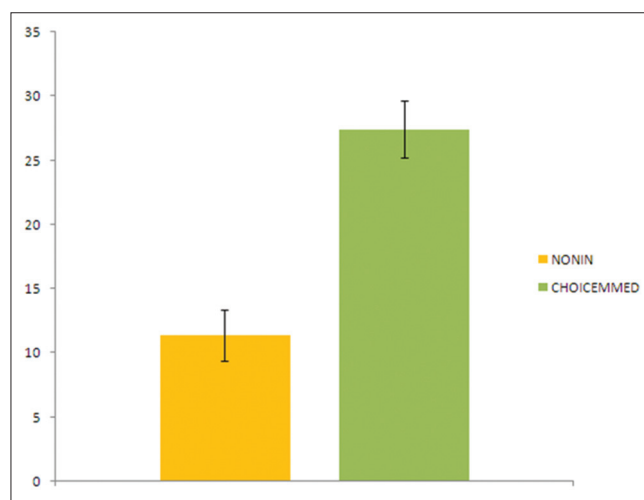


Figure 2: Comparative representation of time to stabilization in both pulse oximeters in seconds

## DISCUSSION

During the study performance of two pulse oximeters under challenging patient conditions was evaluated. While both of the pulse oximeters achieved time to first reading and time to stabilization within 30 s, Nonin medical device outperformed CHOICEMMED device both in time to first reading and time to stabilization of SpO<sub>2</sub> by 1.3 s and 11.4 s respectively. These findings demonstrate that there is variability in performance of the pulse oximetry devices and future clinical validation must be carried out in various settings to verify claims made by manufacturers.

The average time to first reading across all fingers was significantly longer with the CHOICEMMED device ( $10.3 \pm 0.8$  s) as compared to Nonin Medical ( $9.0 \pm 0.8$  s) pulse oximeter. The mean difference was 1.3 s (95% CI, (0.05, 2.61),  $P = 0.04$ ). The average time to stabilization of SpO<sub>2</sub> across all fingers was also statistically significantly longer in the CHOICEMMED ( $27.4 \pm 2.2$  s) pulse oximeter than Nonin Medical pulse oximeter ( $11.4 \pm 2.0$  s). The findings are in accordance with study of errors of pulse oximetry by Severinghaus *et al.* In a study by Macleod *et al.*, it was seen that forehead and ear sensors (central location) had up to six times faster responses to change in ventilation than fingertip oximeter. However, our study focused on fingertip pulse oximeters alone, because of the prevalence in practice which can lead to wider generalization of results. This study is unique in comparing the time to stabilization and first reading of Nonin Medical and CHOICEMMED pulse oximeter. While the Nonin device performed better than CHOICEMMED, we advocate testing these parameters in different challenging clinical settings.

Two major factors might affect the time to stabilization and time for first reading of pulse oximeters, first is proximity to large vessels. The probes which are central in location (forehead, ear, Nasal) and hence closer to great vessels consistently have shown faster response times.<sup>13-16</sup> Signal averaging time also affects the time to stabilization of most pulse oximeters. Signal averaging time is a technique used by pulse oximeters to obtain nonfluctuating measurements. Most new generation oximeters have signal average time <10 s in default states, though they can be calibrated to lesser times as less as 3 s.<sup>14,15</sup> In fact American sleep medicine guidelines recommend signal averaging time <3 s for pulse rate >80 beats/min or higher.<sup>13</sup> Faster response time of the Nonin device might be attributable its better handling of artefacts, low perfusion filter and lower signal averaging times of <3 s at even lower pulse rates of 60 beats/min. Hypothermia, vasoconstriction and low gestation age can also affect time to first reading.<sup>15-17</sup> However, our study was not aimed to detect performance of pulse oximetry in these situations. Similarly finger characteristics such

as deformity, nail pigmentation, and clubbing might also influence the response time. In our study, there was no significant difference in stabilization times across various fingers in both groups of pulse oximeters.

Our study has many strengths, it focuses on a clinically important parameter, which can be of value in situation where emergency assessment of tissue oxygenation is vital to management of rapid sequence and crash intubation.<sup>11,12,18</sup> We also performed these measurements in 'real-world' clinical settings as opposed to hypoxia laboratories. We compared two new generation pulse oximeters to verify their claims. While both of these pulse oximeters had time to stabilization <30 s, Nonin's pulse oximeter performed significantly better. Some weaknesses of the study were open blinded assessment of comparisons. We could not account for more challenging situations like hypothermia and poor perfusion.<sup>19,20</sup> We hope these lacunae would be taken care of in future studies.

## CONCLUSION

We were able to assess the 'real world' performance of two pulse oximeters and determine vital clinical parameters of time to stabilization and time to first reading in both the groups. While time to stabilization was <30 s in both the groups. Nonin's device was almost 2.5 times faster in time to stabilization. The Pulse oximeter (Model 9560) by Nonin Medical showed shorter latency for first reading and time to stabilization when compared to CHOICEMMED (MD300C1), which is a distinct advantage in emergency situations in acute patients. Further, larger studies are needed to validate these findings in different clinical settings. We also recommend testing various pulse oximeters across different clinical settings and in other challenging conditions such as hypothermia, poor perfusion, sepsis, and with vasoconstrictors to enable wider generalization of clinical findings.

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