

Masimo Rad-57 Pulse CO-Oximeter™ for noninvasive carboxyhemoglobin measurement

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Selim Suner[†] and John McMurdy

[†]Author for correspondence
Rhode Island Hospital, Rhode Island Disaster Medical Assistance Team (RI-1 DMAT), NDMS/DHHS, Medical Simulation Center, CORO 106, One Hoppin Street, Providence, RI 02903, USA
Tel.: +1 401 793 8637
Fax: +1 401 444 5456
ssuner@brown.edu

Noninvasive methods of body fluid chemical measurement have been expanding. New technologies are enabling the quantification of different compounds in the blood and interstitial tissues. One example of this is the pulse oximeter, which has facilitated the measurement of oxyhemoglobin rapidly and reliably without the requirement of blood-draws. The Masimo Rad-57 Pulse CO-Oximeter™ expanded the capabilities of pulse-oximetry to include measurements of carboxyhemoglobin and methemoglobin. This innovation has revolutionized the paradigm for detection of patients with CO poisoning. Previously, clinicians relied on historical information and patient signs and symptoms pointing to the possibility of CO exposure or toxicity. Only then would a blood test be ordered to measure carboxyhemoglobin levels. Since the presentation of CO poisoning is nonspecific and overlaps with many other conditions, and since the presence of environmental CO is often unknown, the detection of this condition was only possible in cases where the presence of CO was obvious or where the symptoms were severe. We now know, from studies conducted using the Rad-57, the only US FDA-approved device for noninvasive measurement of SpCO, that there are a significant number of patients who experience CO exposure but are nonsymptomatic. The Rad-57 provides a clinical justification for screening in the healthcare setting to identify patients with significant CO exposure who would otherwise be undetected.

KEYWORDS: carbon monoxide • noninvasive • poisoning • pulse CO-oximetry

Technology

The Rad-57 Pulse CO-Oximeter™ (Masimo, CA, USA) is a rugged, hand-held unit with an LED display and a fingertip clip probe. This is the only device on the market that is US FDA-approved to noninvasively detect carboxyhemoglobin (SpCO). The operation of the device is simple, only requiring the application of the fingertip probe and the pressing of a button to obtain the results in 10 s (FIGURE 1). Understanding the method for adding SpCO measurement functionality to a pulse oximeter as a logical next step for this transcutaneous technology requires a brief discussion of the key principles of pulse oximetry. Three key physiological properties are exploited in conventional pulse oximetry:

- Pulsatile changes in vessel diameter [1];
- Variation in optical absorption of hemoglobin derivatives as shown in FIGURE 2;

- Deep optical penetration depths in tissue for near-infrared and long-wavelength visible light in tissue [2].

A pulse oximeter consists of a light-output diode (emitter) and collection detector at opposed sides of the fingertip. The near-infrared and long-wavelength visible light diffuses through the tissue, interacting with many tissue absorbers, such as blood constituents and skin pigments. One portion of light reaching the detector interacts with the pulsatile varying arteries, causing the amount of transmission to decrease during systole. This decrease is a result of vessel dilation, which subsequently increases the propagation length of light traversing the vessel and, therefore, increasing the optical absorption (although it has also been presented that this variation arises from red blood cell aggregation and release affecting optical scattering [3]). The systemic variation



Figure 1. The Masimo RAD-57 Pulse CO-Oximeter™.

in transmission is the signal that is monitored to quantify pulse and, furthermore, to calculate the arterial oxygen saturation for oxyhemoglobin (SpO_2).

Calculating relative contributions from oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin are based on the Beer–Lambert law, which states that the transmitted intensity (I) at each wavelength of light (λ) is correlated with its initial intensity (I_0), the distance the light travels through the medium (d), the concentration of optical absorbers (c) and the efficiency of their absorption (ϵ). This is represented as the following straightforward equation:

$$I = I_0 e^{\chi p(-\epsilon cd)}$$

Solving for the concentration of oxy-, deoxy- and carboxy-hemoglobin explicitly in this equation becomes difficult as d is highly variable and depends on numerous tissue optical properties, while I_0 may also vary from device to device. The Beer–Lambert law is modified in three ways in a conventional pulse oximeter to rectify these effects.

First, the ratio in transmission from systole to diastole is calculated, not the absolute transmission at one position. As the irradiation intensity is the same in both cases, it is normalized out of the equation. Second, the transmission is calculated in multiple wavelength bands. Assuming a stable relationship between the pathlength d for multiple wavelengths (based on a population average), the pathlength parameter is normalized

out of this second new parameter. What is left is a ratio of ratios, R , at multiple wavelengths during systole (S) and diastole (D), such that:

$$R = (I(\lambda_1, S)/I(\lambda_1, D))/(I(\lambda_2, S)/I(\lambda_2, D))$$

The last step is to extract SpO_2 from this ratio of ratios, made possible by the fact that SpO_2 is itself a ratio, where:

$$\text{SpO}_2 = (\text{HbO}_2)/(\text{HbO}_2 + \text{Hb})$$

Assuming ϵ is dominated by the summation of $\epsilon(\text{HbO}_2)$ and $\epsilon(\text{Hb})$ at both wavelength bands, $(\text{HbO}_2)/(\text{HbO}_2 + \text{Hb})$ can be rewritten in terms of these absorption efficiencies, which are known values, and the ratio of ratios described earlier. Wavelength bands that have highly different absorption efficiencies between the two species are chosen to enhance sensitivity.

Since carboxyhemoglobin is also a ratio value, fractional $\text{COHb} = (\text{COHb})/(\text{COHb} + \text{HbO}_2 + \text{Hb})$, comparable processing steps are taken to the earlier calculation. Additional layers of complexity then arise as, although the same method for initial intensity and pathlength correction are possible, rewriting the equation for COHb becomes less straightforward and requires additional ratio parameters. Subsequently, using the Masimo Rad-57 to measure SpCO or other derivatives requires a modified probe with additional wavelength bands (from 400 to 1000 nm) to increase the number of measurables and more advanced processing algorithms to calculate more complex parameters [4]. Although the Rad-57 uses an eight-diode array, this is probably a result of improved accuracy through some redundancy and the ability to measure other derivatives, such as methemoglobin (SpMet) and

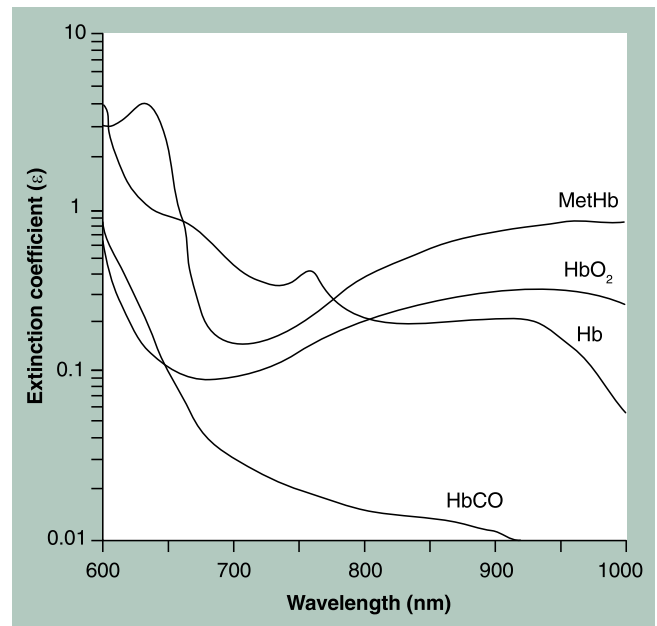


Figure 2. Absorption spectra in the near infrared regime of oxy-, deoxy-, met- and carboxy-hemoglobin.

Hb: Deoxyhemoglobin; HbCO: Carboxyhemoglobin; HbO₂: Oxyhemoglobin; MetHb: Methemoglobin.

Adapted from [1].

total hemoglobin with the same probe. In principle, three bands could be used to derive COHb; however, the similarity of COHb and HbO₂ in the long-wavelength visible region prohibit accurate measurement without additional components.

In the Rad-57 user's manual, Masimo discusses requirements for correct sensor placement and warns against potential inaccurate measurements as a result of significant levels of methemoglobin, motion artifacts, intravascular dyes, abnormal total hemoglobin levels, and abnormally low arterial perfusion [4]. The manual also discloses specifications of SpCO measurement range from 1 to 99%, with an accuracy of $\pm 3\%$ for one standard deviation verified in healthy adult volunteers with SpCO levels ranging from 1 to 40%. In addition to the COHb measurement capability, the Masimo Rad-57 also employs signal extraction technology, improving the accuracy of the device by isolating changes in optical properties from arterial blood in the presence of nonarterial blood movement. This is achieved through digital filtering and parallel engines, including discrete fourier transforms, to only isolate the arterial pulsatile variation that is desired [4].

Clinical significance

Carbon monoxide (CO) is a gas that poses serious threats to health and life. The gas is produced whenever there is combustion of carbon-containing material (e.g., wood, oil, kerosene and charcoal) CO is ever-present throughout the world. It is produced in homes that use fuel for heating or hot water; whenever a barbecue is lit, while we enjoy the ambiance of the fireplace (either gas- or wood-burning); and when a generator or car engine is running. In most cases, CO is ventilated out of dwellings, vehicles and enclosed spaces (e.g., hockey rinks and stadiums) by an exhaust system or chimney. If the space is not enclosed, it simply diffuses into the atmosphere and rarely reaches sufficient concentrations to induce CO poisoning. If not properly ventilated (e.g., owing to faulty heaters, clogged vents or chimneys), the gas can accumulate, become concentrated and enter the circulatory system during normal ventilation without warning, where it attaches to red blood cells, muscles and other cells, mostly causing dysfunction to the nervous system and heart.

Known as the 'invisible killer', CO exposure results in an estimated 15,000 emergency department visits, causes 500 unintentional deaths each year and is the leading cause of accidental poisoning deaths in the USA [5]. When inhaled, CO displaces oxygen in the blood and, therefore, deprives the heart, brain and other vital organs of life-sustaining oxygen.

Carbon monoxide is particularly dangerous as this gas cannot be seen or felt; has no smell or taste and, until there is sufficient accumulation in the body tissues, one cannot know that they have been breathing

it. Furthermore, signs of early poisoning can be mistaken for other common ailments, such as influenza, since it causes headache, nausea, vomiting and generalized weakness. If not treated at this stage, CO will continue to poison the body and can lead to death or severe neurological damage.

The best solution to CO poisoning is prevention. There is a three-pronged approach to managing CO poisoning: education; proper installation and maintenance of CO-producing devices; and detection.

Prevention starts with understanding the dangers of CO and the possible sources that can generate the gas. Proper installation of heating and cooking systems and regular maintenance of these mechanical systems is essential to preventing accumulation of CO in dwellings, work places and community gathering sites. Finally, although CO is odorless, tasteless and invisible to the human eye, there are simple and relatively inexpensive detectors (similar to smoke detectors in homes) that can sense the presence of CO in the atmosphere and set off an alarm. Installation of these detectors in homes is an essential part of prevention.

Early detection of CO exposure in patients can lead to earlier treatment and improved outcomes. Currently, the diagnosis of CO poisoning relies on a blood test. Depending on size and location of the hospital, the results of this test may take hours to obtain. Some hospitals may even lack the capability to measure COHb concentrations in blood [6]. Furthermore, since the test requires a blood draw, large-scale surveillance for CO poisoning is not commonly performed. The Masimo RAD-57 device, utilizing an eight-wavelength probe, allows for the noninvasive measurement of blood SpCO and methemoglobin saturation noninvasively in approximately 10 s. This technology has provided a cost-effective clinical justification for CO-poisoning screening.

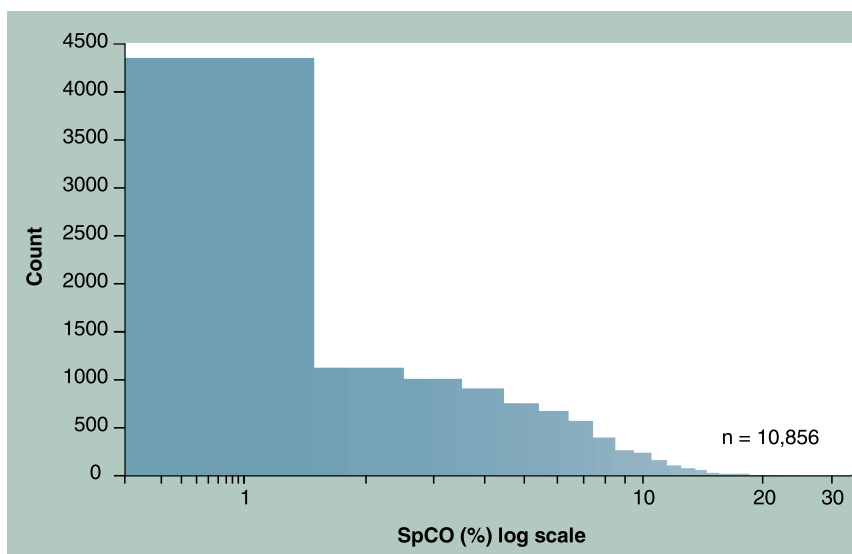


Figure 3. Distribution of SpCO values among patients visiting the emergency department. The x-axis represents a log scale of SpCO and bars on the y-axis represents the frequency for each value. A total of 10,856 patients were screened. SpCO: Carboxyhemoglobin.

The mainstay of treatment of patients poisoned with CO is oxygen. Increasing the fraction of inspired oxygen in the inhaled gas above ambient levels has a significant impact on CO clearance. Oxygen removes CO molecules, which compete for and displace oxygen molecules normally bound to hemoglobin. CO binds to blood cells, muscle cells and other organelles in the body. In mild cases of CO poisoning, oxygen can be given using a face mask in the emergency department. In severe cases, prolonged oxygen delivery as required and hospital admission may also be required. Pressurized oxygen delivered via a hyperbaric chamber may be required. Although many patients with mild or moderate CO poisoning will recover, some patients may develop long-term neurological, psychiatric or cardiac conditions from CO poisoning [7]. Approximately half of patients who have severe poisoning (those who are unconscious, have seizures or heart attacks from CO exposure) will either have severe long-term illness or will die. CO is the most frequent killer of all poisons worldwide.

Clinical studies

Since this technology is fairly new, only a handful of clinical studies have been published. Investigators used a convenience sample of 31 subjects who were having arterial blood analysis to correlate SpCO and SpO₂ to arterial blood CO-oximetry. All but one of these subjects had clinically normal COHb levels. The data show that, although well correlated to the CO-oximeter values, both SpCO and SpO₂ were slightly overestimated by the Rad 57 [8].

In a study with ten healthy volunteers, Barker *et al.* obtained serial SpCO measurements (37 data points) using the Rad-57 and correlated these values to arterial blood samples analyzed in a CO-oximeter for COHb, while the subjects inhaled CO at 300 ppm. The maximum COHb value in this study of induced CO toxicity was approximately 15%. The precision of the device for measuring carboxyhemoglobin was 2.19%. The data, plotted on a graph with COHb on the x-axis and SpCO on the y-axis, suggest that the variance increases with higher levels of COHb. Bland–Altman analysis could be used to better characterize these data, particularly the effects of different concentrations of COHb on variance [9].

The first documented use of the Rad 57 in the clinical setting was in a patient who suffered CO toxicity as a result of a house fire. Investigators recorded two sets of COHb values using standard CO-oximetry on blood and followed the SpCO over 150 min with 18 data points using the Rad 57. The initial SpCO was recorded as 39% with the blood CO-oximeter showing 35% and the final readings were 6 and 5% for SpCO and COHb, respectively. The investigators were able to monitor the elimination of CO from the body in this patient treated with 100% oxygen via an endotracheal tube and concluded that the elimination was zero order.

Prior studies have shown that first-order elimination of CO occurs with more aggressive hyperbaric oxygen therapy. Furthermore, once again, the SpCO slightly overestimated the true COHb concentration in this study [10].

In a similar study using healthy volunteers in a laboratory setting, Barker *et al.* obtained samples from ten subjects and concluded that, for the detection of methemoglobinemia, the Masimo Rad-57 had a precision of 0.5% and correlated well with CO-oximetry of blood sampled from the radial artery ($r = 0.985$). However, when observing the data, it appears that the variance increases with increasing methemoglobin levels. Again, a Bland–Altman plot would have been a better method to evaluate these data [11,12].

Pulse CO-oximetry has also been used in detecting smokers. From a study population that included 306 self-reported nonsmokers, 72 second-hand smokers and 98 smokers, investigators were able to calculate the sensitivity, specificity and predictive value of the Rad-57 SpCO and SpMet to detect their smoking status. There were significant differences in both SpCO and SpMet between smokers and nonsmokers and also between smokers and second-hand smokers. The investigators calculated a sensitivity of 46% and a specificity of 95% for detecting smokers, using a SpCO cut-off of 6% [13].

Clinical studies from the Rhode Island Hospital emergency department

When the Masimo Rad-57 was introduced, the authors recognized the potential this device had for studying large populations for CO toxicity. We set out to design a paradigm where the Rad-57 was used to collect SpCO measurements on every patient who entered the emergency department at Rhode Island Hospital, which is the largest emergency department in southern New England (USA) with an adult census of over 102,000 patients per year in 2007, in practical terms rendering SpCO a vital sign, similar to blood pressure and pulse. We trained the emergency department nurses and technicians performing triage and recording vital signs in the operation of the

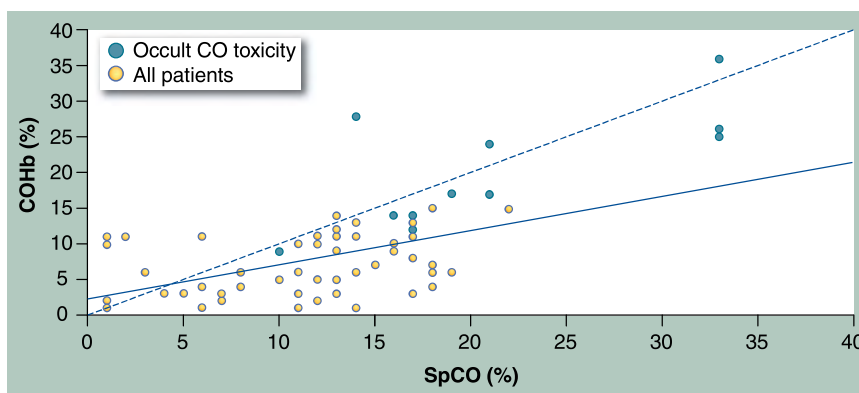


Figure 4. Carboxyhemoglobin as measured by the Rad-57, plotted on the x-axis as percent against COHb, with carboxyhemoglobin obtained by blood test on the y-axis. The darker circles denote patients with occult CO toxicity, and the O symbol represents all patients who had both SpCO and COHb measurements. The dotted line is the identity line. All points would fall on this line if SpCO predicted COHb perfectly. The solid line is a linear regression to all points with $r = 0.72$, $p < 0.01$. CO: Carbon monoxide; COHb: Carboxyhemoglobin obtained by blood test; SpCO: Carboxyhemoglobin measured by the Rad-57.

device and supplied ample Rad-57 devices in the triage areas for measuring both SpO₂ and SpCO as well as heart rate. Our trained research assistants obtained the data from previous days' charts, which were electronically archived. The data consisted of SpCO and 17 other variables, including COHb if obtained. Patients identified with CO toxicity were interviewed either immediately in the emergency department or by telephone using a standard instrument.

During a 2-month period, we were able to obtain SpCO measurements in 10,856 patients, accounting for 75% of all patients presenting to the emergency department. Although 75% was a good capture rate it was below other, more established vital signs, such as blood pressure and heart rate (~90% capture rate). We attributed this to the novelty of the measurement at triage. Overall, the mean SpCO was $3.6 \pm 3.3\%$, with a median of 2% and a wide range of 0–33% (FIGURE 3). Self-declared smokers had a significantly higher SpCO (mean: 5.2%).

The most striking result from this investigation was the identification of 11 patients (over an 8-month period, including the 2-month period discussed previously) who had significant CO toxicity, which would otherwise have been missed if SpCO was not measured at triage. These patients presented to the emergency department with complaints that were not related to CO toxicity. These 11 patients represent 40% of all patients who were diagnosed with CO toxicity during the 8-month study period. As previously reported, the Rad-57 overestimated the COHb levels in our study (FIGURE 4); however, the device characteristics were fairly reliable compared with the 'gold-standard' blood COHb, as described in the Bland–Altman plot (FIGURE 5) [14].

In an effort to elucidate the characteristics of patients presenting with occult CO toxicity, 15 patients with occult CO toxicity presenting to the emergency department at Rhode Island Hospital in a 13-month period were identified through population screening with the Rad-57 at triage, and their presentations documented with follow-up interviews. This study demonstrated that, by having the Rad-57 available at triage and screening all patients presenting to the emergency department, clinicians were able to identify cases of CO poisoning that would otherwise have gone undetected. Furthermore, in some of the cases presented, the detection of high SpCO in a patient led to the discovery of CO toxicity in their spouse and identification of elevated environmental CO in their home, thereby preventing exposure of others [15]. The patients identified with occult CO toxicity did not have the common presentation of poisoning or symptoms that are commonly attributed to other diagnoses (e.g., influenza-like illness). Although a formal cost–benefit analysis was not undertaken, the cost of screening all patients in the emergency department is probably low compared with the potentially devastating morbidity or mortality of missing a few patients with unsuspected

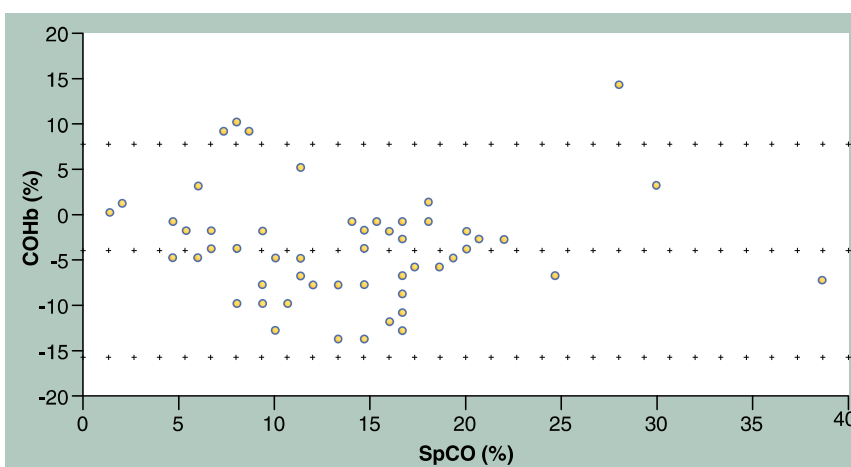


Figure 5. Bland–Altman plot showing mean carboxyhemoglobin and COHb on the x-axis and the difference between SpCO and COHb on the y-axis for patients who had both SpCO and COHb measured. The middle line, denoted with +, is the mean difference, the upper and lower lines are mean +2 standard deviation, representing the limits of agreement. The mean difference is -4.2% with a 95% confidence interval of -2.8–5.6%; difference SpCO–COHb is calculated as COHb - SpCO. COHb: Carboxyhemoglobin obtained by blood test; SpCO: Carboxyhemoglobin measured by the Rad-57.

CO exposure. The cost of the device, service and probe wear and tear should outweigh the cost of missing several cases of CO toxicity with long-term neuropsychiatric or cardiovascular morbidity and mortality. The cost of nursing time and documentation is negligible as the device also measures SpO₂ and heart rate, which are recorded at triage points as standard procedure.

Expert commentary

Masimo has revolutionized detection of hemoglobins with the introduction of the Rad-57 device, which initially measured SpCO concentrations. SpMet and total hemoglobin detection are other available noninvasive measurements. Now, all three can be measured using a single device. While applications for SpMet and total hemoglobin are being evaluated, there is clear evidence that noninvasive measurement of SpCO has been instrumental in identifying patients with unsuspected CO poisoning and hidden sources of CO [14,15]. This device is an important tool for public health. Theoretically, methemoglobin trends can be used in the management of sepsis and fluid management in pediatric diarrheal illness and other causes of dehydration. Continuous total hemoglobin may be useful in the operating theater, where blood loss and transfusions are common. Continuous, real-time, noninvasive monitoring of hemoglobins is novel and their utility in patient care will continue to be defined by future studies.

Five-year view

Following the trend after incorporation of simple pulse-oximeters into medical practice, the Masimo Pulse CO-Oximeter will probably be used at the entry points to the healthcare system, such as emergency departments, clinics and doctors offices, where SpCO, SpMet and total hemoglobin will be among the vital signs recorded.

This device may be incorporated into the emergency medical services system and be utilized in the disaster setting. Furthermore, this device will probably find uses in remote and austere locations where medicine is practiced [16].

Financial & competing interests disclosure

Both authors are founders and shareholders of Corum Medical Inc., which is a company involved in the development of noninvasive hemoglobin monitors. Suner is a patent holder for a method of determining hemoglobin noninvasively. Neither the patent nor the product developed by Corum Medical Inc. are

directly related to the Masimo device and utilize different methods of estimating hemoglobin. Some data in the studies conducted by Brown University were obtained through loaned equipment from Masimo. Also Masimo funded a portion of the research assistants to collect the data. The investigators did not receive any funds from Masimo. The data remain the sole property of the investigators in the Brown University studies. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

Key issues

- Carbon monoxide (CO) poisoning is the leading cause of death and disability from toxins.
- There are currently three methods of detecting carbon monoxide in the blood: CO-oximetry on blood, breath analysis and fingertip pulse CO-oximetry.
- While breath analysis is also noninvasive, it is highly effort-dependent and has not been widely accepted in clinical practice, leaving the Masimo Rad-57 Pulse CO-Oximeter™ the only device for measuring carboxyhemoglobin noninvasively.
- Studies conducted to date demonstrate that carboxyhemoglobin recorded with the Masimo Rad-57 device correlates well with blood CO-oximetry but slightly overestimates CO-levels.
- Since CO poisoning presents with a variety of nonspecific signs and symptoms that could easily be mistaken for influenza or other illness, universal screening for this disease can identify patients who have unsuspected toxicity.
- Early detection of CO-poisoning can lead to improved outcomes for the patient and may prevent others from being exposed to an unsuspected source of CO.

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Affiliations

- Selim Suner, MD, MS
Associate Professor, Brown University; and, Director, Disaster Medicine and Emergency Preparedness, Department of Emergency Medicine; and, Chairman, Emergency Preparedness Committee, Rhode Island Hospital, Rhode Island Disaster Medical Assistance Team (RI-1 DMAT), NDMS/DHHS, Medical Simulation Center, CORO 106, One Hoppin Street, Providence, RI 02903, USA
Tel.: +1 401 793 8637
Fax: +1 401 444 5456
ssuner@brown.edu
http://research.brown.edu/myresearch/Selim_Suner
- John McMurdy, PhD
Division of Engineering, Box D, Brown University, Providence, RI 02906, USA
Tel.: +1 401 863 3078
john_mcmurdy@brown.edu