Reliability of new pulse CO-oximeter in victims of carbon monoxide poisoning.

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M. COULANGE[1], A. BARTHELEMY[1], F. HUG[2], A.L. THIERRY[1], L. DE HARO[3]

[1] Réanimation Médicale et Hyperbarie, Hôpital Sainte Marguerite, Marseille, Fr, [2] Université de Nantes, Laboratoire JE 2438, Nantes, Fr, [3] Poison Center, Marseille, Fr

Coulange M, Barthelemy A, Hug F, Thierry AL, De Haro L. Reliability of new pulse CO-oximeter in victims of carbon monoxide poisoning. Undersea Hyperb Med 2008; 35(2):107-111. Study objective: The purpose of this study was to evaluate the reliability of noninvasive real-time measurement of carboxyhemoglobin (COHb) using a pulse CO-oximeter in victims of carbon monoxide poisoning (COP). Methods: During the 7-month study period, pulse CO-oximetry was measured on patients admitted to the emergency department (ED) for suspected COP. Each patient included in the study underwent concomitant assessment of COHb by blood sampling and noninvasive pulse CO-oximetry (SpCO). Results: Twelve non-smoker patients were included. Mean age was 40 ± 17 years. No difference was found between the two COHb assessment techniques ($p>0.05$). Analysis using the Bland and Altman procedure suggested good alignment of the two techniques with a slight bias (i.e. -1.5%) indicating slight overestimation by the pulse CO-oximeter. Analysis using the Passing and Bablok statistical protocol further documented the reliability of the two methods. Conclusion: This study documents the precision of the correlation between readings obtained with the noninvasive pulse CO-oximeter and COHb measurements from blood samples. This preliminary result demonstrates that this simple rapid noninvasive technology could be useful before and after arrival at the ED.

INTRODUCTION

Carbon monoxide (CO), one of the most common causes of fatal poisoning in Western countries (1), requires emergency therapy. Hyperbaric oxygen therapy (HBO_2) is the gold-standard treatment in severe cases and can decrease the incidence of cognitive sequelae (2). However there are no clear guidelines for the use of HBO_2 due to variations in clinical presentation, discrepancies between clinical and laboratory findings and, above all, pitfalls in documenting elevated carboxyhemoglobin (COHb) levels. Some authors have found no consistent correlation between clinical signs and COHb concentration (1) but typically a COHb concentration above 25% is considered as sufficient to indicate HBO_2 in a patient with or without severe symptoms (2). Thus there is an urgent need for a reliable technique which measures COHb level. Currently detection of CO in ambient air using portable electrochemical sensors provides an effective method of preventing accidental exposure but there is no simple method of evaluating the extent of individual poisoning. Performing measurements on expired air requires special operator training and patient cooperation. In addition, expired air measurement, although highly cost-effective, is unsuitable for use during emergency rescue due to poor sensitivity and specificity, technical complexity and long calibration time (3). Analysis of blood samples is a rapid and easy-to-perform invasive technique for routine in-hospital measurement of COHb level provided that the necessary equipment is available, well maintained and properly calibrated. However it can provide misleading results if the time interval between exposure and blood sampling in the emergency department (ED) or between

blood collection at the rescue scene and assay in the hospital is prolonged. The purpose of this study was to evaluate the reliability of pulse CO-oximetry technology for noninvasive real-time measuremnt of COHb level in victims of carbon monoxide poisoning (COP).

METHODS

Study setting and design

This study was carried out at the Hyperbaric Center at Sainte Marguerite Hospital in Marseille, France. Pulse CO-oximetry was proposed to patients treated for COP in the ED from October 2005 to April 2006. After informed consent was obtained, noninvasive assay was performed in combination with standard work-up procedures without changing therapeutic strategies (according to French law, no ethics committee advice was necessary). For the child included in the study, the parents' consent was obtained. This prospective descriptive study was undertaken independently, with no funding from the device manufacturer. It was not designed as a clinical trial.

Patient selection

Patients admitted to the ED with suspected COP but prior to blood sampling and hospital admission were included in the study. Smokers were excluded.

Methods of measurement and data collection

All patients included in this study were managed as usual for COP: physical examination, electrocardiography, chest x-ray and typical laboratory tests were conducted. Measurement of COHb level was performed by a nurse under physician supervision using the standard spectrophotometric measurement on a venous blood sample (IL 682 CO-oximeter, Instrumentation Laboratory, Barcelona, Spain) at the same time as measurement using a Rad-57 pulse CO-oximeter (SpCO) (5) (Masimo Corporation, Irvine, CA, USA). In addition to measuring conventional pulse oximetry variables, the FDA-approved Rad-57 system uses 8 wavelengths of light for rapid (within seconds) noninvasive measurement of COHb via a sensor placed on the middle or ring finger (6). The COHb level is expressed in percent of total hemoglobin.

Measurement results

Table 1 lists COHb data and presents the symptoms of each patient studied. Clinical signs were scored as absent; minor, i.e., headache, dizziness, nausea, vomiting, weakness; and severe, i.e., confusion, loss of consciousness, coma, hypotonia, convulsions, and precordialgia.

Table I. Relations between clinical seriousness and carboxyhemoglobin levels obtained with invasive (COHb) and simultaneous pulse CO-oximetry (SpCO) measurement (n = 12).

Subjects	Gender	Age (YO)	First clinical signs	Dosage (%)	
				COHb	SpCO
1	Male	8	Absent	1.2	4
2	Pregnant woman	30	Minor	2.6	6
3	Male	20	Minor	10.2	13
4	Female	27	Severe	10.7	9
5	Female	50	Minor	11.0	15
6	Female	69	Severe	11.3	10
7	Female	35	Minor	11.9	12
8	Male	53	Severe	17.6	18
9	Female	51	Severe	18.0	20
10	Male	38	Absent	20.1	25
11	Male	51	Minor	20.8	18
12	Male	56	Minor	31.6	35

First clinical signs: absent; minor, i.e., headache, dizziness, nausea, vomiting, weakness; and severe, i.e., confusion, loss of consciousness, coma, hypotonia, convulsions and precordialgia.

Data analysis

Data analysis was performed using the MEDCALC statistical package for

windows (version 8.1.1, Medcalc, Belgium). A Kolmogorov-Smirnov test was used to check normal data distribution. All values were reported as means ± standard deviation (SD). The level of significance was 0.05.

Differences between COHb levels measured using the conventional technique and pulse CO-oximetry were assessed using a paired t-test. Method reliability was assessed as described by Bland and Altman (7). Mean difference (bias) and SD of the differences between the values obtained using the two methods were calculated. Data was plotted graphically to allow a comparison between the differences with mean values in %. Mean differences were plotted on graphs.

The statistical protocol described by Passing and Bablok (8) were used to test the equality of values obtained using the two techniques. After testing the linearity of the relationship between values, confidence limits were computed for the slope beta and intercept alpha. These limits were used to assess whether the difference between beta and 1 and between alpha and 0 were random.

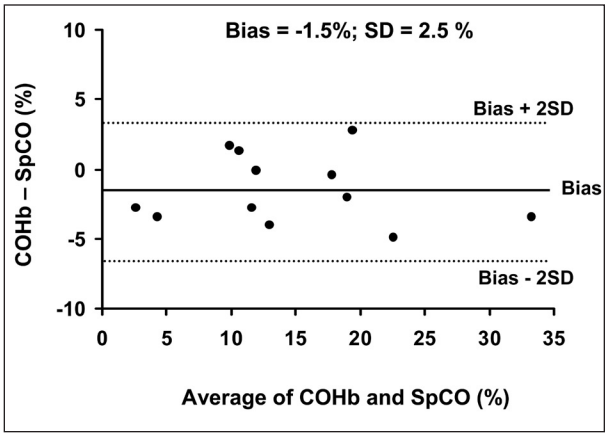
RESULTS

During the 7-month study period, twelve patients admitted to the ED for suspected COP were also monitored with the pulse CO-oximeter. Table I presents the characteristics of these patients along with the results of the two COHb assays and the initial severity of symptoms. Mean patient age was 40 ± 17 years with an equal proportion of men and women. One woman was pregnant. Three patients had COHb levels above 20% (using the standard spectrophotometric measurement on a venous blood sample) without severe clinical symptoms. Conversely four of the remaining 9 patients with COHb levels below 20% presented severe symptoms.

Mean COHb values were 13.9 ± 8.3% and SpCO values were 15 ± 9%. The difference between these two means was not significant ($p>0.05$). Analysis using the Bland and Altman protocol (7) demonstrated good alignment for both techniques (figure 1A) with a bias of -1.5% suggesting that pulse CO-oximetry slightly overestimated. The analysis using the Passing and Bablok statistical protocol (8) also demonstrated good alignment (figure 1B).

The 12 patients included in the study recovered rapidly and left the hospital after 24 hours of observation.

A



B

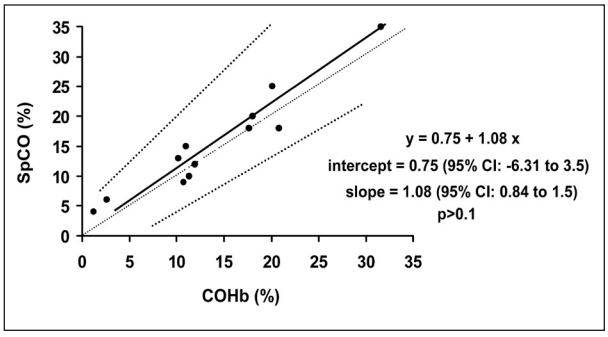


Fig. 1. COHb vs SpCO (n = 12). A: Comparison of the difference between COHb and SpCO with the average of COHb and SpCO (Bland and Altman plot). B: Comparison of SpCO with COHb (Passing and Bablok regression).

LIMITATIONS

A major limitation of this study was patient recruitment. This problem was related to the number of available pulse CO-oximeter devices, which was insufficient to allow routine SpCO assay at each time venous blood was collected. A more widespread use of this technology should expand the patient database.

From a more practical standpoint, it should be noted that to use the device correctly, particularly the finger sensor, requires training and practice. The manufacturer emphasizes that there are several known causes of potentially incorrect readings such as placing the finger improperly in the sensor, intense ambient light or high levels of methemoglobin. In our study, poor signals were obtained from the sensor for a patient with false fingernails and a small infant. A pediatric sensor will soon be available.

DISCUSSION

This study is the first report correlating the SpCO value from the Rad-57 with blood COHb measured on a laboratory CO-oximeter in the real world setting (ED) and not in laboratory experiment. Values measured in this study ranged from 1.2% to 31.6%. All previous articles demonstrating the reliability of noninvasive assessment have involved smokers (5, 6) or healthy volunteers (9) breathing 500 ppm of carbon monoxide with COHb levels below 15%. Noninvasive measurement of COHb using a pulse CO-oximeter provides instantaneous readings. This is an advantage not only for prompt diagnosis but also in the choice of therapy for patients with minor or no clinical symptoms. Indeed, our results confirm that there is no correlation between carbon monoxide concentration and severity of the symptoms (Table I). Weaver et al. documented the benefit of HBO in preventing neurological sequelaes in patients with COHb levels above 25% with or without severe symptoms (2). These findings underline the need for quick accurate assessment of COHb levels even for patients with seemingly minor symptoms. Pulse CO-oximeter could satisfy this need with a slight but acceptable measurement bias (figure 1A). Pulse CO-oximetry provides a means of early recognition of severe poisoning thus optimizing ED decision-making.

In this clinical series no false positive readings were obtained with the pulse CO-oximeter compared to the COHb. This differs from the findings of O'Malley (10), who reported a number of false positives. The company gave several explanations for the initial false readings (10) as already mentioned, including the problem of finger position in the sensor, presence of methemoglobin, sickle cell or hemolytic anemia (11), ambient light or dark patient skin pigment. O'Malley does not take into account these factors in his report.

Our data indicate that pulse CO-oximetry could be useful for the management of COP in two possible situations. First in hospital emergency departments, pulse CO-oximetry would accelerate detection time of COHb levels. More reliable and cost-effective than conventional laboratory techniques, CO-oximetry could be used for routine measurement of COHb in all patients admitted to the ED (12). Routine screening would be an excellent tool to reduce the misdiagnosis rate especially for patients who present non-specific symptoms (13). Pulse CO-oximetry technology could also be used to perform serial or continuous readings to ascertain therapeutic compliance.

Although not tested in this study, a second situation that could benefit from the use of pulse CO-oximetry is emergency rescue and transportation. Since this technology is portable, it could be used for differential

diagnosis for patients presenting non-specific symptoms, neuropsychiatric signs, gastrointestinal symptoms, chest pain, collapse or smoke inhalation. Pulse CO-oximetry seems more suitable for disaster situations than measurement of CO in expired air since it does not require patient cooperation or calibration between measurements. Furthermore CO readings from exhaled air expressed in ppm may be affected by recent ingestion of alcohol. Another point is that the automatic conversion of CO levels to percentage of COHb does not take into account a number of important variables such as ventilatory parameters, partial pressure in pulmonary capillaries, hemoglobin level, cardiac output, blood pH and endogenous CO production. It is also worth noting that although blood sampling at the emergency scene is highly recommended in cases involving COP, it is subject to a number of operational constraints. When taken, samples are rarely used due to prolonged delay or doubts concerning quality (3). In situations involving household poisoning, pulse CO-oximetry would allow prompt differential diagnosis between food-born intoxications and carbon monoxide exposure and facilitate triage especially for patients with low-grade symptoms.

This study documents the good alignment between readings obtained with a pulse CO-oximeter and COHb measurements from blood samples. The findings of this study demonstrate that simple rapid noninvasive technology is reliable both before and after arrival at the ED.

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