Performance of the RAD 57 Pulse Co-Oximeter Compared With Standard Laboratory Carboxyhemoglobin Measurement: A Review of the “Touger” Article and Recommendations for EMS/Fire Agencies

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Purpose of This Discussion

• To review the rationale for measuring carbon monoxide levels in the out-of-hospital setting.
• To discuss the recent literature on the performance of the RAD 57.
• To help EMS/Fire agencies understand how this study may impact utilization of the RAD-57.
Carbon Monoxide Poisoning and Emergency Responders
Carbon Monoxide

• Colorless, odorless, tasteless, toxic gas.

• Leading cause of death due to poisoning in industrialized nations

• Even at low levels, CO may cause long-term cardiovascular and neurological disorders.

• CO is a serious and sometimes deadly threat both in the home and on the fire ground.

• Firefighters and paramedics have regular contact with carbon monoxide at fire and rescue scenes, increasing their health risks.
Carbon monoxide (CO)

- Until recently, the only way to reliably diagnose CO poisoning was to draw blood and check the CO levels in a lab.

- With the introduction of the Masimo Rad-57, testing for CO can be done quickly and easily, allowing for prompt screening and treatment.
Incomplete combustion of any carbon-based material will produce carbon monoxide. Closed or confined spaces are particularly hazardous. Common sources are:

- Automobiles, trucks, buses
- Boats, campers
- Gas heaters, furnaces, and hot water heaters
- Gas-powered generators
- Small gasoline engines
- Portable / space heaters
- Barbecues / fireplaces
- Cigarette smoke
- Lanterns
- Methylene chloride (paint stripper)
  - Liver converts to CO
- Structure / wild land fires
# Signs and Symptoms

<table>
<thead>
<tr>
<th>SpCO (%)</th>
<th>Clinical Manifestations</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4%</td>
<td>None - Normal</td>
</tr>
<tr>
<td>5-9%</td>
<td>Minor Headache</td>
</tr>
<tr>
<td>10-19%</td>
<td><strong>Headache, Shortness of Breath</strong></td>
</tr>
<tr>
<td>20-29%</td>
<td><strong>Headache, Nausea, Dizziness, Fatigue</strong></td>
</tr>
<tr>
<td>30-39%</td>
<td>Severe Headache, Vomiting, Vertigo, ALOC</td>
</tr>
<tr>
<td>40-49%</td>
<td>Confusion, Syncope, Tachycardia</td>
</tr>
<tr>
<td>50-59%</td>
<td>Seizures, Shock, Apnea, Coma</td>
</tr>
<tr>
<td>60% -up</td>
<td>Coma, Death</td>
</tr>
</tbody>
</table>

USE OF THE RAD-57

Many fire and EMS agencies now carry this device and routinely use it in the assessment of patients as well as during rehab operations on the fire ground.
RAD-57 Pulse CO-Oximeter

- The Masimo RAD-57, FDA approved in 2005, is the world’s first and only Pulse CO-Oximeter
  - Measures pulse rate, CO level and spMet level
- FDA approved

- Uses a finger probe to provide a non-invasive measurement of COHb

- The device is non-invasive, fast and portable

- It projects various wavelengths of light through the nail bed of the finger to measure the COHb level
  - similar technology as the pulse oximeter, although the RAD-57’s finger probe is much “less forgiving” than that of a standard pulse oximeter.

-Masimo reports accuracy of +/- 3%
Performance of the RAD-57 Pulse Co-Oximeter Compared to Standard Laboratory CO Measurement

Analysis of a Recent Study by Dr. Micheal Touger et al: Ann Emerg Med 2010;56:382-388
Results of the Touger Study

- Study included 120 subjects
- Conducted in the emergency department at Jacobi Medical Center in the Bronx, NY (Albert Einstein School of Medicine)
  - COHb ranged from 0 to 38% (median lab 2.3%, median RAD 3%)
  - 23 patients characterized by levels >15%
  - Limits of agreement of measurement differences between SpCO and COHb were -11.6% to +14.4%
  - Lab SpCO <15%, RAD COHB identified 96/97
    - Reported specificity of 99%
  - LAB SpCO >15% RAD COHB identified only 11 of 23 patients
    - Reported sensitivity of 48%
• The outliers circled in red are significantly different than other available studies of 1,690 subjects, and are also significantly different than Masimo’s internal testing of 3,629 measurements.
• The authors separated subjects with COHb values over 15% and showed the reported Rad-57 SpCO measurements in those cases

**Touger Study Table on COHb >15%**

<table>
<thead>
<tr>
<th>Laboratory COHb (%)</th>
<th>SpCO (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.8</td>
<td>0</td>
</tr>
<tr>
<td>35.2</td>
<td>0</td>
</tr>
<tr>
<td>20.5</td>
<td>13</td>
</tr>
<tr>
<td>16.9</td>
<td>14</td>
</tr>
<tr>
<td>16.2</td>
<td>6</td>
</tr>
<tr>
<td>18.3</td>
<td>9</td>
</tr>
<tr>
<td>16.4</td>
<td>14</td>
</tr>
<tr>
<td>22.9</td>
<td>13</td>
</tr>
<tr>
<td>15.1</td>
<td>8</td>
</tr>
<tr>
<td>15.9</td>
<td>3</td>
</tr>
<tr>
<td>18.8</td>
<td>11</td>
</tr>
<tr>
<td>18</td>
<td>0</td>
</tr>
</tbody>
</table>

*In Masimo's opinion, based on internal testing of over 3,629 measurements, it is not likely for a functioning Rad-57 device and sensor to produce these results when the directions for use are followed, contraindications are excluded, sufficient statistical sampling is conducted, and the measurements are compared to simultaneous COHb levels.*
Summary of Published Studies on SpCO Accuracy

Table 1. Results of Independent Studies comparing SpCO to COHb

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Setting</th>
<th># of Subjects</th>
<th>Limits of agreement for SpCO vs. COHb (%)</th>
<th>Bias (%)</th>
<th>Precision (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mottram et al(^8)</td>
<td>2005</td>
<td>Respiratory Department</td>
<td>31</td>
<td>-1.5 to +5.5</td>
<td>2.0</td>
<td>1.8</td>
</tr>
<tr>
<td>Coulange et al(^9)</td>
<td>2008</td>
<td>Emergency Department</td>
<td>12</td>
<td>-6.4 to +3.4</td>
<td>-1.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Kot et al(^10)</td>
<td>2008</td>
<td>Hyperbaric Center</td>
<td>49</td>
<td>-7.9 to +8.9</td>
<td>0.5</td>
<td>4.3</td>
</tr>
<tr>
<td>Piatkowski et al(^11)</td>
<td>2009</td>
<td>Burn Center</td>
<td>20</td>
<td>-1.5 to +7.8</td>
<td>3.2</td>
<td>2.4</td>
</tr>
<tr>
<td>Roth et al(^12)</td>
<td>Pending Publication</td>
<td>Emergency Department</td>
<td>1,578</td>
<td>-3.4 to +9.4</td>
<td>3.0</td>
<td>3.3</td>
</tr>
<tr>
<td>Suner* et al(^2)</td>
<td>2008</td>
<td>Emergency Department</td>
<td>64</td>
<td>-15.9 to +7.5</td>
<td>-4.2</td>
<td>5.9</td>
</tr>
<tr>
<td>Touger et al(^6)</td>
<td>2010</td>
<td>Emergency Department</td>
<td>120</td>
<td>-11.6 to +14.4</td>
<td>1.4</td>
<td>6.6</td>
</tr>
</tbody>
</table>

* The reported mean time difference between SpCO measurements and venous blood draws used for COHb measurements was 67 minutes, preventing the results from being used to examine SpCO accuracy.
Published Studies on SpCO Accuracy


Potential Reasons for Discrepancies Between Touger et al Results and Other Studies

- Possible reasons for discrepancies include multiple items addressed in the directions for use of the device and sensor, including:
  - Device or sensor malfunction
  - Inappropriate finger positioning in sensor (finger positioning away from the digit stop will result in incorrect SpCO measurements)
  - Using an inappropriately-sized sensor for size of subject’s finger
  - Timing of SpCO and COHb measurements not being exactly simultaneous (Because the half life of COHb is 74 minutes on 100% oxygen, and it drops exponentially), or inadequate calibration of the lab machine.
  - Elevated methemoglobin, bilirubin, or hypoxia.
  - Patient motion and external light interference.
Isaacs/Eckstein’s Recommendations

- EMS leaders need to read the peer reviewed literature.
- EMS/Fire agencies should continue to utilize the RAD-57 as an adjunct in the evaluation of pts and providers who may have been exposed to CO.
- EMS personnel should ALWAYS use a light shield when measuring CO with the RAD-57.
- If the results of the Touger study are accurate, reproducible and generalizable, then the low sensitivity suggests that the RAD-57 cannot reliably exclude CO poisoning in any pt with appreciable risk of being poisoned.
- If a patient/provider is exhibiting signs/symptoms of CO poisoning they should be transported to an emergency department for further evaluation, regardless of the RAD-57 reading.
- Maintain some healthy skepticism until further data is published!
Thank You for Your Attention !!!