Performance of the RAD-57 Pulse CO-Oximeter Compared with Standard Laboratory Carboxyhemoglobin Measurement.

Touger M., Birnbaum A., Wang J., Chou K., Pearson D., Bijur P. Ann Emerg Med. 2010 Oct;56(4):382-8.

Study Objective

We assess agreement between carboxyhemoglobin levels measured by the Rad-57 signal extraction pulse CO-Oximeter (RAD), a Food and Drug Administration-approved device for noninvasive bedside measurement, and standard laboratory arterial or venous measurement in a sample of emergency department (ED) patients with suspected carbon monoxide poisoning.

Methods

The study was a cross-sectional cohort design using a convenience sample of adult and pediatric ED patients in a Level I trauma, burn, and hyperbaric oxygen referral center. Measurement of RAD carboxyhemoglobin was performed simultaneously with blood sampling for laboratory determination of carboxyhemoglobin level. The difference between the measures for each patient was calculated as laboratory carboxyhemoglobin minus carboxyhemoglobin from the carbon monoxide oximeter. The limits of agreement from a Bland-Altman analysis are calculated as the mean of the differences between methods ± 1.96 SDs above and below the mean.

Results

Median laboratory percentage carboxyhemoglobin level was 2.3% (interquartile range 1 to 8.5; range 0% to 38%). The mean difference between laboratory carboxyhemoglobin values and RAD values was 1.4% carboxyhemoglobin (95% confidence interval [CI] 0.2% to 2.6%). The limits of agreement of differences of measurement made with the 2 devices were -11.6% and 14.4% carboxyhemoglobin. This range exceeded the value of \pm 5% carboxyhemoglobin defined a priori as clinically acceptable. RAD correctly identified 11 of 23 patients with laboratory values greater than 15% carboxyhemoglobin (sensitivity 48%; 95% CI 27% to 69%). There was one case of a laboratory carboxyhemoglobin level less than 15%, in which the RAD device gave a result greater than 15% (specificity of RAD 96/97=99%; 95% CI 94% to 100%).

Conclusion

In the range of carboxyhemoglobin values measured in this sample, the level of agreement observed suggests RAD measurement may not be used interchangeably with standard laboratory measurement