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Analytical Instrument Performance Criteria

On-Site Measurement of Blood-Lead Concentrations Using Field-Portable Electroanalysis

Kevin Ashley, Ph.D., Column Editor

Reported by Lauralynn Taylor, Robert L. Jones, and Kevin Ashley

The health effects of lead exposure are well documented. Lead can be inhaled into the lungs, absorbed through the skin, or ingested from contaminated hands, food, or cigarettes. Because air samples are not a surrogate for biological monitoring, Occupational Safety and Health Administration (OSHA) regulations mandate that employees' blood-lead levels be tested regularly.[1] Given the high potential for surface contamination, venous samples are considered the primary method for blood-lead testing in occupationally exposed individuals. Currently, OSHA regulations do not mandate a specific analytical method for blood-lead analysis. Instead, successful participation in an ongoing proficiency-testing program is necessary to remain CLIA- (Clinical Laboratory Improvements Amendment[2]) certified and OSHA-approved in blood-lead analytical techniques. CLIA mandates that a blood-lead analysis laboratory must report proficiency testing results within ±4 μg/dL (±0.19 μmol/L) or within 10 percent, whichever is greater, of the target (true) value.[2]

In recent years, different technologies have been investigated for their utility as portable blood-lead analysis instruments. Portable instruments are potentially useful because they provide immediate results and the opportunity for immediate intervention, if necessary. Instruments involving both Potentiometric Stripping Analysis (PSA) and Anodic Stripping Voltammetry (ASV) have been explored.[3]

An instrument utilizing PSA is in commercial development by Intelab Corporation (Mission Viejo, CA). Although some preliminary field evaluations have been conducted with the PSA instrument, this device has not been submitted for FDA (Food and Drug Administration) market clearance.[4] Hence, this article discusses only an ASV instrument that has received market clearance.

ESA, Inc. (Chelmsford, MA) and AndCare, Inc. (Durham, NC) developed a small, rapid, handheld portable instrument utilizing ASV. This device, named the LeadCare® instrument, has received 510(k) market clearance from the FDA and has been classified under CLIA as a moderately complex medical diagnostic device.[5] It has been used with success during pediatric screening programs.[6] However, blood-lead levels in children are generally significantly lower than the blood-lead levels normally present in occupationally exposed adults. Thus, it was of interest to evaluate the portable blood-lead monitor in worker populations where lead exposures are encountered.

Basic Operating Principles

The LeadCare® portable ASV instrument uses electrochemistry with a small, screen-printed colloidal gold electrode to measure the amount of lead in whole blood.[7] The operational range of the LeadCare® instrument is 2 μg/dL to 65 μg/dL (~0.1 μmol/L to ~3.1 μmol/L), which should encompass the vast majority of employee blood-lead levels encountered in the United States. The FDA market clearance of the portable ASV instrument excludes all blood-lead samples below the limit of detection. If a blood sample contains a lead concentration greater than 65 μg/dL, the instrument responds with the message "HI" in the digital display.

To begin analysis with the LeadCare® instrument, 50 microliters of fresh, whole blood are mixed with a proprietary treatment reagent (ESA, Inc.). This reagent disrupts the red blood cells that contain lead and chemically disassociates the lead from the red blood cell components. "Free" lead is released in the treatment reagent in the form of divalent lead. This lead species is then available for detection on the sensor electrodes.

After the blood-treatment reagent mixture is transferred to the sensor and the test is started, an electrical potential is applied by the analyzer, which causes the lead to collect (plate) onto the test electrode. The analyzer then causes the removal (stripping) via a potential (voltage) sweep to more positive potentials. The resultant current associated with stripping is then measured and automatically converted into a blood-lead concentration value (μg/dL), which is displayed on the analyzer.[5] This technique is known as Anodic Stripping Voltammetry (ASV).[3,7]

Evaluation

Given the potential challenges of an occupational environment, it was deemed necessary to evaluate the ASV instrument in a workplace setting. This evaluation has been published in detail elsewhere[8] and is presented briefly herein. Industries historically associated with lead exposure, such as battery manufacturing, abrasive blasting in construction, and lead smelting, were contacted to participate in this study.

Each of two participating employees donated two 2-mL venous samples for the study. Each blood sample was

drawn into a Vacutainer™ tube (containing EDTA) identified by a bar-coded identification label. The samples were immediately placed in a rocker to prevent clotting of the blood. One tube from each sampling pair was refrigerated and sent via overnight courier to the Centers for Disease Control and Prevention (CDC) reference laboratory. These samples were analyzed for blood-lead using graphite furnace atomic absorption spectrometry (GFAAS; Perkin-Elmer Model 4100-ZL GFAAS with Zeeman-effect background correction) based on the method described by Miller et al.[9] GFAAS was considered the (true) reference analytical method.

Calibrations were uploaded onto each instrument every time the instrument was turned on, and were repeated if a new reagent test kit was opened. LeadCare® quality control samples were analyzed on each instrument at the beginning and end of each analytical session. Quality control samples consisted of two blood-lead concentrations: 7.0 μg/dL and 25.8 μg/dL.

Method Comparison

A total of 208 eligible study participants were recruited from the two industrial sites. Two participants were excluded from the analysis because they had blood-lead levels below the limit of detection (1.4 μg/dL) of the portable ASV instrument. The statistical analyses were conducted based on the differences between the two analytical methods. Because the differences between the two methods were nearly normally distributed, a logarithmic transformation was not conducted on the differences. The mean difference between the blood-lead levels obtained from the portable ASV instrument and GFAAS was 0.79 μg/dL (standard deviation [SD] = 5.59; p = 0.0436), indicating that, on average, the portable ASV instrument overestimated the true blood-lead value by less than 1 μg/dL.[8]

The differences between the portable ASV instrument and the GFAAS blood-lead analyses are plotted against the GFAAS blood-lead results (considered the "true" blood-lead concentration) in Figure 1. Approximately 95 percent (196/206) of the data points fell within $\pm$11 μg/dL, and the differences between the two techniques remained relatively consistent over the range of observed blood-lead concentrations. However, it is important to note that although the mean difference was less than $\pm$1 μg/dL, nine data points overestimated the true blood value by greater than 11 μg/dL. Surface lead contamination on workers' skin could be responsible for some outliers, wherein one of the paired blood samples could have become contaminated during sampling. A simple linear regression detected a statistically significant association between the portable ASV instrument and the laboratory results (see Figure 2).

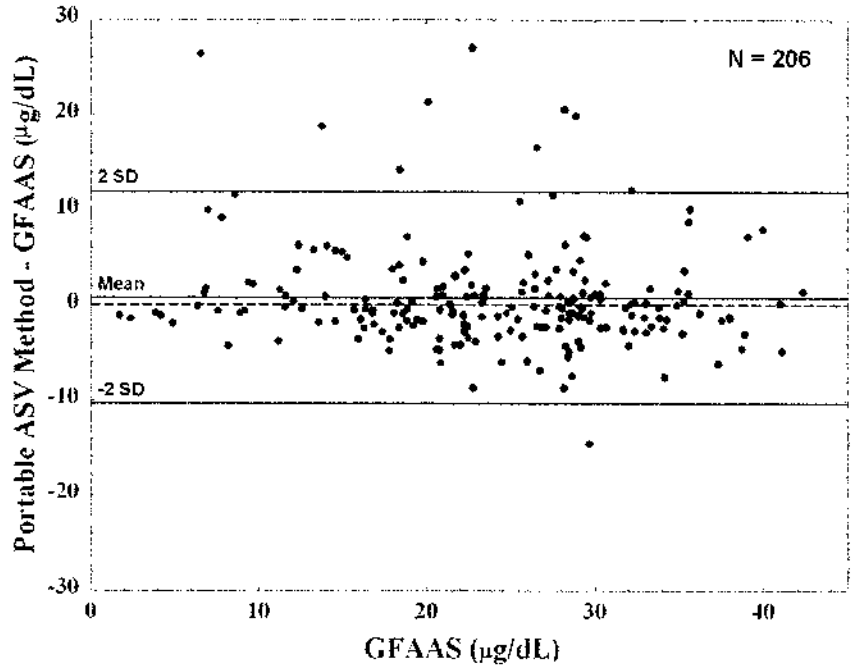

FIGURE 1
Differences between the portable ASV instrument and GFAAS as measured against GFAAS.

Quality control samples were analyzed to estimate the instrument's precision. Table I presents the mean precision and standard deviation for the two quality control standards. The bias or mean percent difference between the portable ASV results and the GFAAS results is presented in Table II. This analysis indicates that the results from the field instrument yielded a slight positive bias overall (p = 0.0213), with less bias for blood-lead levels above 10 μg/dL (p = 0.0738). (It is noted, however, that the observed bias for blood-lead levels below 10 μg/dL was negligible for samples obtained from a large data set of children).[6]

Comparison of Portable ASV and GFAAS

The portable ASV instrument has a working range of 2 μg/dL to 65 μg/dL, while GFAAS has a normal calibration range of 1 μg/dL to 50 μg/dL and an effective "working range" of ~1 μg/dL to 300 μg/dL (with appropriate dilutions). The limit of detection (LOD) of the portable ASV instrument is 1.4 μg/dL, while the GFAAS has an LOD of 0.3 μg/dL. Overall, GFAAS has approximately twice the precision of the LeadCare® instrument. Although ASV precision is lower, the portable ASV instrument still has significant value as an analytical tool in blood-lead analysis.

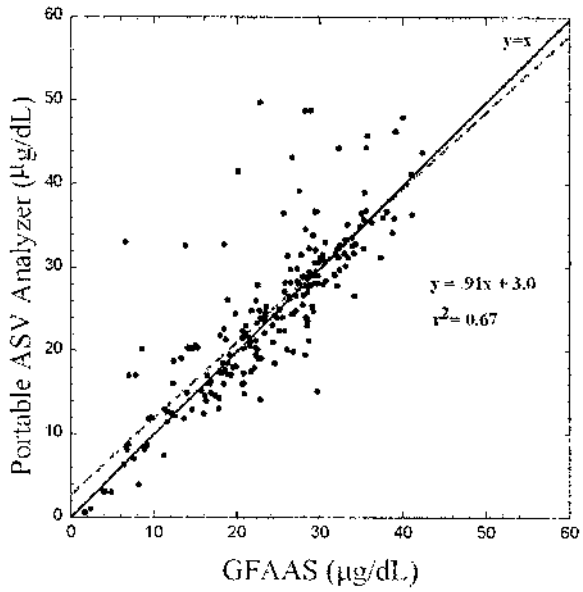

FIGURE 2
GFAAS laboratory method versus portable ASV analyzer method.

The investment cost of this instrument is relatively low in comparison to the traditional GFAAS equipment. Depending on the volume of samples analyzed, the cost per sample of ASV analysis is less than, or comparable to, GFAAS analysis.

CLIA Certification Requirements

The LeadCare® portable ASV instrument requires the user to be CLIA-certified for moderately complex testing. Obtaining CLIA certification is a resource-intensive process, and should be fully considered when evaluating the potential use of this instrument in an occupational setting.

Compliance Uses

Under current interpretations, if a facility successfully participates in the proficiency-testing program using the LeadCare® instrument, then those portable ASV results could be used for OSHA compliance.[10] Despite less frequent requirements mandated by OSHA, many employees participate in monthly or bimonthly blood-lead monitoring programs offered by their employers. Therefore, if a facility is CLIA-certified, the portable ASV instrument could also be utilized during noncompliance monitoring periods. The portable ASV device could be especially useful for monitoring workers who are hard to track, such as construction workers on-site, or workers in a "clean" van or "mobile laboratory."

State Reporting Requirements

Currently, many states operate registry programs that require approved blood-lead laboratories to submit adult blood-lead results to the state health department when the levels are above a mandated level. There is concern among state surveillance officials that widespread utilization of the portable ASV instrument could cause a bypass of the current registry systems. Although this is a possibility, there is little reason to believe that a laboratory utilizing the portable ASV instrument would be less likely to abide by state reporting requirements than a laboratory utilizing alternate analytical methods.

Study Limitations

Manufacturer specifications indicate that the LeadCare® instrument has a working range from 1.4 μg/dL to 65 μg/dL. Therefore, this evaluation cannot comment on the instrument's performance above a blood-lead concentration of 42 μg/dL, since this was the highest concentration observed in the present evaluation.[8] However, an evaluation of populations with workers at higher blood-lead concentrations could be conducted, and is an opportunity for additional research.

TABLE I
Blood-lead quality control standards and estimated precision

Quality control standard (levels)	N	Mean ± standard deviation (μg/dL)	Precision (RSD*)
Level 1	30	7.4 ± 1.4	0.19
Level 2	30	25.8 ± 2.1	0.08

*RSD = Relative standard deviation

TABLE II
Estimated bias of LeadCare® portable ASV instrument

Blood-lead range	N	Mean percent difference (bias) ± SD*	p-value
BLL ≤ 10.0 μg/dL	16	0.45 ± 1.1	0.1252
BLL > 10.0 μg/dL	190	0.03 ± 0.2	0.0738
Overall	206	0.06 ± 0.4	0.0213

*SD = Standard deviation

Summary

The portable ASV instrument was evaluated using worker populations, and observed results were within the blood-lead range of 1.4 μg/dL to 42.0 μg/dL (see Figures 1 and 2). The mean difference between the results of the field

instrument and those of the laboratory analysis was less than 1 μg/dL. Given that treatment options would not be dramatically altered by a change in blood-lead of $<\pm 1$ μg/dL, the mean difference between the two analytical methods holds very little clinical significance. It is unclear why the portable ASV instrument occasionally overestimates the blood-lead levels by greater than ± 11 μg/dL. In this data set, 9 out of 10 data points outside two standard deviations from the mean resulted in an overestimation of the true blood-lead level. Additional evaluation of the portable ASV device is underway. Occupational health professionals should evaluate the occurrence of these values when determining if the ASV instrument is appropriate for their applications.

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Mention of company or product names does not constitute endorsement by the Centers for Disease Control and Prevention (CDC).