Assessment of two diabetes point-of-care tests in the Peruvian Amazon

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The performance of the DCA Vantage and Afion point-of-care (POC) devices were analyzed in the Peruvian Amazon by comparing the hemoglobin A1C (HbA1C) results to laboratory-confirmed values using high-performance liquid chromatography (HPLC).

METHODOLOGY

- Intravenous blood samples were collected from 187 subjects in the communities of Huepetuhe (85), Quebrada Nueva (32), Caychihue (16), Setapo (2), Puquiri (4), and Quince Mil (48) using randomized sampling methods.
- Samples were stored between 2-8°C in EDTA-containing tubes and shipped to a central location in Mazuco, where HbA1C was measured using the DCA Vantage (Siemens Medical Diagnostics Solutions, Puteaux, France) and Afion (Alere Inc., Waltham, Massachusetts) POC devices.
- Precision analysis was conducted by measuring one sample 14 consecutive times by each device.
- Samples were then shipped to Lima, where HbA1C was measured at the Medlab clinical laboratory using HPLC.

RESULTS

- The within-sample coefficient of variation (CV) using repeated measures was 4.01% for the DCA Vantage and 1.75% for the Afion.
- The mean difference between the DCA Vantage and the HPLC was +0.32 [95% confidence interval (CI): +0.29, +0.35; p <0.001].
- The mean difference between the Afion and the HPLC was +0.57 [95% CI: +0.54, +0.60; p <0.001].
- The linear regression models for the DCA Vantage (Figure 1) and Afion (Figure 2) produced coefficient of determination (r²) values of 0.8616 and 0.8395, respectively.
- The 95% limits of agreement for the mean difference between the DCA Vantage and the HPLC were -0.08 to +0.72 (Figure 3).
- The 95% limits of agreement for the mean difference between the Afion and the HPLC were -0.18 to +0.67 (Figure 4).

CONCLUSIONS

- The statistically and clinically significant differences in the performance of the DCA Vantage and Afion devices when compared to the gold-standard HPLC method indicate that caution should be exercised when relying on POC devices to measure HbA1C in clinical settings in the Amazon.

PROJECT OBJECTIVES

- Measure the precision of the DCA Vantage and Afion devices.
- Assess the accuracy of the DCA Vantage and Afion devices.

Study Sites

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