RAPID Results

Rapid A1c Point-of-Care In Diabetes: Evaluation of Current Point-of-Care A1c Machines

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Are you looking for quicker way to assess your patients with diabetes on a routine basis?

Point-of-care (POC) testing is performing any laboratory test outside the main laboratory. An emerging POC test is the use of glycosylated hemoglobin A1c (A1c) machines for routine evaluation of a patient’s diabetes control. If a patient misses a routine A1c test designated for the laboratory, the patient and the physician may not be able to assess the patient’s diabetes. Thus in this situation, POC A1c machines can provide a rapid A1c value for the ongoing treatment of diabetes.

Point-of-care testing of A1c in the clinical setting can be rapidly performed (3-11 minutes) using a fingerstick to help guide clinical decision-making. POC A1c have been shown to improve patient management in diabetes clinics and improve A1c values in some patient populations. The A1c results through point-of-care instruments can increase clinical effectiveness and improved outcomes. However, it is also important that the device be accurate and precise.

The eight most commonly available machines are listed in Table 1 along with their manufacturers, CLIA-Waived, time to results, and how much whole blood is needed. In this article, we evaluated and compared the current A1c point-of-care machines available in the United States using a primary literature review was conducted using Pubmed to compare the current A1c point-of-care machines. The MeSH terms used for the literature search were “reproducibility of results”, “point-of-care systems/standards”, and “hemoglobin A, glycosylated.” MeSH terms were combined and search limits included “human” and “within the last five years.”

Based on the literature search, eight journal articles were found of which two were relevant. One article compares the eight most commonly used A1c POC instruments in the United states using accepted analytical performance criteria established by the National Glycohemoglobin Standardization Program (NGSP) including EP-10, EP-5, and EP-9 shown in Table 1. Preliminary analyses of general performance were evaluated using EP-10 criteria. Two of the manufacturers pulled their A1c machines from the study due to poor results in the EP-10

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<th>Table 1: POC A1c Instruments at a Glance and NGSP Criteria</th>
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<tr>
<td><strong>POC A1c Instruments (Manufacturer)</strong></td>
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<tr>
<td>In2it™ (Bio-Rad)</td>
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<tr>
<td>DCA Vantage™ (Siemens)</td>
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<td>NycoCard (Axis- Shield)</td>
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<td>Afinit™ (Axis- Shield)</td>
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<td>Clover (Infopia)</td>
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<td>InnovaStar (DiaSys)</td>
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<td>A1CNow™ (Bayer HealthCare)</td>
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<td>Quo-Test™ (Quotient Diagnostics)</td>
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Note: To pass the NGSP Criteria at least one pass must be present in each lot number.
outcomes data. Of the remaining six A1c machines, specific precision and accuracy tests were evaluated based on EP-5 and EP-9 criteria, respectively. These secondary analyses were conducted three times each in two different lot numbers. Only two of the A1c POC instruments passed NGSP criteria in both lot numbers (DCA Vantage™ and Afinion™).  

The second article compares the accuracy and precision of two POC instruments (DCA Vantage™ and the Afinion™) against a laboratory high performance liquid chromatography method. Both the DCA Vantage™ and the Afinion™ machines showed a strong correlation (r=0.70) with the laboratory value. DCA Vantage™ mean difference from the POC instrument to the traditional laboratory method was 0.28% with P value <0.0005 and correlation coefficient of 0.973. Afinion™ mean difference from the PCOT instrument to the laboratory method was 0.27% with P value <0.001 and correlation coefficient of 0.991. Thus, both machines A1c were comparable to the laboratory value.

Utility in Outpatient Management of Diabetes
The 2013 ADA guidelines indicate that point-of-care A1c machines should not be used for diagnostic purposes. However, the UKPDS showed that a 1% difference in A1c can show statistically and clinically important differences in risks for complications. As per 2013 ADA guidelines, A1c should be checked twice a year for patients who at their glycemic goal and four times a year for patients who have not meet their glycemic goal. If several routine labs are being obtained from patients (e.g., lipid profile, complete metabolic panel), then the POC A1c may not be needed. However, if the patient has missed a lab or home monitoring of blood glucose does not seem to coincide with patient symptoms and control, then POC A1c may be useful. While acquiring POC machine and testing supplies/strips would require an initial investment, A1c values may be billed when performed in office.

Summary
To be an effective point-of-care A1c machine, it is important for the A1c test to provide accurate results comparable to laboratory analysis. It is important to keep in mind that A1c point-of-care machines should help guide therapy for control and treatment; however, clinical decisions should not be placed solely on point-of-care A1c machines. Overall, A1c POC testing machines allow for rapid testing and are appropriate for evaluating the control of diabetes but not for the diagnosis of diabetes.

REFERENCES

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