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ORIGINAL ARTICLES

Analysis of Office-Based Glycohemoglobin Measurement

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Abstract

Hemoglobin A1c (HbA1c) measurements are important for monitoring glycemic control in patients with diabetes. The positive impact of point-of-care HbA1c measurements on patient management is described in the literature. The general analytical requirements for HbA1c testing are described. The analytical evaluation of a new point-of-care HbA1c analyzer, suitable for a physician's office, against these requirements is described.

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Introduction

Based on large-scale epidemiological studies, hemoglobin A1c (HbA1c) measurements have come to play a critical role in the monitoring of glycemic control in patients with both type 1 and 2 diabetes.[1,2] This critical role necessitated improvements in both the accuracy and the imprecision in the analytical measurement of HbA1c. Substantial improvements in the analytical performance of HbA1c measurements compared with a decade ago have been made and this is due, in large part, through the efforts of the National Glycohemoglobin Standardization Program (NGSP).[3,4] In addition, the National Academy of Clinical Biochemistry (NACB) has published guidelines[5] for the measurement of HbA1c, which include the setting of imprecision goals similar to those recommended by other authors.[6–8] The guidelines also recommend some quality assurance parameters that are intended to improve the quality of reporting HbA1c results.

The impact of point-of-care HbA1c measurement has been established by several authors.[9–12] Increased patient compliance (as measured by a decrease in patient HbA1c values) and increased patient and physician satisfaction make the introduction of point-of-care HbA1c measurements desirable.

Point-of-care analyzers, such as the Bayer DCA 2000+ or Bio Rad D10, for HbA1c measurements may be suitable for larger physician offices and smaller hospitals but are probably too large for individual physician offices.

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Abbreviations: (HbA1c) hemoglobin A1c, (NACB) National Academy of Clinical Biochemistry, (NGSP) National Glycohemoglobin Standardization Program

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The article by Mattewal and colleagues in this issue of the Journal of Diabetes of Science and Technology describes an analytical evaluation of a small HbA1c analyzer, the Metrika A1cNow® InView™, suitable for individual physician offices. This device is a development of an earlier device manufactured by the same company.

The imprecision of the test at an HbA1c level of 9.1% was 2.7%. Data indicate that this is a within-run rather than total imprecision and that the number of data points is below that usually accepted for precision studies. The NACB recommendation, as well as conventional laboratory methodology, is that two levels of control are run for imprecision measurements for HbA1c analysis. HbA1c results produced on the device show acceptable comparison with those generated by the NGSP but only borderline correlation with a laboratory method. However, it must be noted that this equivalence of results was obtained on samples from 1 day and does not reflect day-to-day changes in either the Metrika or laboratory systems.

The authors themselves point out several major shortcomings in their study. The first is that the study was performed by an individual, a Metrika sales representative, who should be familiar with and probably well trained in the operation of the analyzer. Higgins[13] has pointed out that many evaluations of point-of-care instruments are performed by skilled technologists and may not reflect performance by untrained personnel. However, in a study involving experienced and inexperienced technologists and nurse educators, he noted that excellent imprecision and equivalence of results with a reference method were obtained by these three groups using a Bayer DCA 2000+ for both HbA1c and microalbumin/creatinine ratio measurements. It would be useful if the study of analytical performance on the A1cNow InView device was performed using different personnel with different levels of laboratory expertise in different settings.

The other shortcomings in the study, again pointed out by the authors, are that preanalytical blood collection was excluded in the study and that only precollected blood samples for laboratory measurement of HbA1c were used. Laboratorians are becoming increasingly aware of the significant variance in laboratory results that may be obtained as a result of differences in the preanalytical blood collection phase. The importance of a correct specimen collection cannot be overestimated. The milking of the figure producing incorrect glucose results on point-of-care glucose meters is a well-documented preanalytical problem. It is necessary to simultaneously collect a blood sample for laboratory measurement of HbA1c and a sample for the A1cNow InView to truly validate the equivalence of results on the device with laboratory methods. Furthermore, this blood collection should be performed by office personnel who ultimately will be using the device.

The limited data on precision, the sample used for comparison purposes, and the skill of the individual performing the A1cNow InView limit the usefulness of this study for validating this device for the measurement of HbA1c in the physician's office. However, despite these limitations, the authors demonstrated that this device has the potential to be used in physician offices for the measurement of HbA1c. The impact of seeing a test performed in the patient's presence is something that needs to be evaluated. The excuse that "the laboratory analyzed the wrong sample or performed an incorrect analysis" cannot be used when confronted by a result obtained in the presence of the patient. It would be interesting to see if there is an increase in physician and patient satisfaction using a survey similar to that used by Shepard and co-workers[9] following introduction of this device in the physician's office. The impact on patient management, as measured by a decrease in a patient's HbA1c, would be another worthwhile study.

From an overall perspective, the measurement of HbA1c in a physician's office will probably not follow the NACB guidelines for the performance of HbA1c assays. These recommendations include performance of quality control on two levels of control at regular intervals, participation in a College of American Pathologists quality control program, and repeat performance of HbA1c testing if the value is below the reference interval or above a value of 15%. The impact on patient care by noncompliance with these guidelines will possibly be minimal. Nevertheless, there will be the perception, at least in the eyes of laboratory personnel, that physician office testing for HbA1c is inferior to that performed by a laboratory because of the lack of quality control and assurance regimens.

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