POC testing instruments for diagnosing and monitoring diabetes in clinical settings

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Abstract

POC HbA1c is commonly used for monitoring of diabetes mellitus. In a monitoring situation more emphasis is usually placed on precision and less on trueness. Concerning HbA1c, however, one can argue that the same quality specifications should be used both for monitoring and diagnosing since many of the recommendations for good practice deal with absolute HbA1c numbers and not only "improvement" or "deterioration" of the diabetic condition. An expert committee officially recommended to use HbA1c for the diagnosis of diabetes in 2009 (1). There are several advantages using HbA1c compared with glucose such as pre-analytical stability of the sample and low within-subject biological variation of HbA1c (1). Furthermore, HbA1c is stable throughout the day and fasting and dietary restrictions are therefore avoided. World Health Organization (WHO) recommends an HbA1c level of 6.5% (48 mmol/mol) as the cut off point for diabetes, and the assays must be "standardized to criteria aligned to the international reference values" (2). The College of American Pathologist (CAP) recommends that the EQA acceptable limits for accuracy should be 7% in 2012 and 6% in 2013 compared to a target value (6). Furthermore, NACB recommends a within-laboratory CV <2% and a single method should have a between-laboratory CV <3% (3). All CVs are based on the DCCT (Diabetes Control and Complications Trial)/NGSP units (3). It is well known that these CVs will be higher if IFCC (mmol/mol) units are used since the NGSP units are not on the ratio scale. NACB recommends using hospital laboratory HbA1c instruments for diagnosis of diabetes since POC HbA1c assays are "currently not sufficiently accurate for this purpose" (3). It is interesting that when using glucose for diagnosing and monitoring diabetes no quality specifications have be set except for glucometers for self-monitoring and for glucometers in critical care units. Whether the POC instruments should be used for monitoring or diagnosing, within-subject biological variation is of great importance, both from "healthy" people and from stable diabetic patients. We have found that the within-subject variation for HbA1c is 1.2% and 1.7% for healthy and diabetes patients respectively. The corresponding numbers for glucose is 5.4 and 30.5% (4). To be able to judge if POC instruments can be used for diagnosing and monitoring, it is important to look at results from studies where a) the instruments are evaluated under optimal conditions, b) the instruments are evaluated in the hands of the users and c) the instruments are evaluated after they have been on the market for some time, for example the performance in an EQA scheme.

A recently published study evaluated 7 HbA1c POC instruments and concluded that Afinion, DCA Vantage, Cobas B101, and B-analyst instruments met the generally accepted performance criteria for HbA1c. Quo-Test, Quo-Laboratory, and InnovaStar met the criteria for precision but not for bias. The paper also concluded that roficiency testing should be mandated for users of HbA1c POC assays to ensure quality (5). This study was based on laboratory experiments following the CLSI EP-5 guidelines and not longitudinal results from clinical practice. In a recent study (6) results from 13 HbA1c external quality assurance surveys (EQAS) during six years in from both GPs offices using POC instruments and from hospital laboratory instruments were compared with the recommended analytical quality specifications for using HbA1c diagnostically for diabetes mellitus. All General Practice and hospital laboratories measuring HbA1c in Norway participated in the EQAS. Between 60 - 90% of Afinion and DCA users and hospital laboratories performed HbA1c measurements within the quality specifications for both trueness (6.0%) and imprecision (CV ≤ 2.0%) in two levels in each EQA survey.

In conclusion, results indicate that POC instruments for HbA1c can be very useful for monitoring and diagnosing diabetes mellitus. The same is true for POC glucometers although usually not quality specifications are set for the use of these instruments in all different clinical situations. However, a presupposition for using these POC instruments for diagnosing and monitoring diabetes mellitus is that a stringent quality assurance program is established to monitor the quality.

References

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