OBSERVATIONS

Point-of-Care Measurements of HbA_{1c}: Simplicity Does Not Mean Laxity With Controls

Point-of-care HbA_{1c} measurements (POC-A1Cs) have been adopted by many diabetes clinics to improve the quality of care provided to their patients (1). Herein, we show that reliability of this approach might be questioned. POC-A1Cs routinely used in the ambulatory section of our diabetes clinic was evaluated on 100 diabetic patients (type 1, $n = 58$; type 2, $n = 42$) attending the clinic from 1 October 2011 to 30 November 2011. Patients with abnormal hemoglobin traits or shortened erythrocyte life span were excluded. Blood-capillary samples were analyzed by POC-A1C (DCA Vantage; Siemens Medical Solutions Diagnostics, Cergy-Pontoise, France) and venous EDTA-anticoagulated blood specimens by the central laboratory high-performance liquid chromatography measurement (Tosoh HLC-723 GHb G8; BioSciences, Lyon, France). Both methods were certified (NGSP/Diabetes Control and Complications Trial [DCCT] and International Federation of Clinical Chemistry and Laboratory Medicine [IFCC]). Internal quality evaluation showed CVs consistently below 3%.

HbA_{1c} values obtained from POC-A1C were found to be below those given by the central laboratory in 98% of the cases. POC-A1C values differed by a mean of $-0.50 \pm 0.28\%$. Central laboratory and the POC-A1C values were correlated, but the regression equation suggested a slight proportional bias (slope: 0.87) and a greater constant bias (intercept with *y*-axis: 0.37%). Bland-Altman statistics showed a significant correlation between the delta and the mean of HbA_{1c}. The higher the HbA_{1c} value was, the greater the discrepancy between both methods. To evaluate whether these discrepancies in HbA_{1c} values can interfere with decision making, we assessed the possible POC-A1C–induced errors in categorization at the different HbA_{1c} threshold levels used by the clinicians to modify hypoglycemic treatment. If the therapeutic HbA_{1c} objective was ≤6.5%, then 11% of the population was incorrectly considered in the target by POC-A1C. This proportion of misclassification increased to 24% when the therapeutic target was ≤7% and decreased thereafter (≤7.5%, 12%; ≤8.0%, 8%). The higher misclassification rate observed for a 7% threshold is due to the fact that the proportion of patients around this value is especially high in our unselected cohort (HbA_{1c} median: 7.28%). This real-life analysis differed from bench tests, which are usually performed to validate POC-A1C methods (2). Similar tendencies to an underevaluation of HbA_{1c} by POC methods have been noted already by Holmes et al. (3) and by Twomey et al. (4) in the context of the U.K. "pay-for-performance program." At the time of the current study, no sign of a possible drift in HbA_{1c} determination was given by external quality-control procedures. One cannot minimize the clinical relevance of this transitory drift observed with the POC-A1C device. The solution for maintaining routine POC-A1C use involves every participant in the chain. First, lot-to-lot stability must be improved and controlled by the manufacturer as already suggested by Little et al. (5). External quality-control procedures should be more frequent and reactive. Clinicians should be aware of any discrepancies between POC-A1C and central laboratory values and, if necessary, carry out a local audit as we did. Finally, it should be dangerous to rely only upon POC-A1C to evaluate the quality of long-term glucose control in diabetic patients. Measurement of HbA_{1c} by laboratory method should be performed at least once a year.

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