Journal of Diabetes Science and Technology
Volume 7, Issue 5, September 2013

LETTER TO EDITOR

Analytical Performance and Clinical Use of a Hemoglobin A1c Point-of-Care Analyzer in a Pediatric Unit

Anne Marie Dupuy, M.D., Ph.D., Cécile Elong-Bertard, Pharm.D., Stéphanie Badiou, Pharm.D., Ph.D., Amandine Barrot, Pharm.D., Anne Sophie Bargnoux, Pharm.D., Ph.D., and Jean Paul Cristol, M.D., Ph.D.

The implementation of point-of-care (POC) analyzers in the clinical department is growing. However, Lenters-Westra and Slingerland's study[1] on several POC tests for hemoglobin A1c (HbA1c) highlighted the necessity to evaluate the accuracy of each POC device. The aim of our study is to assess the analytical performance of DCA-Vantage® from Siemens, France, including (1) imprecision, (2) effects of presence of variants on the results of HbA1c, (3) correlation with central laboratory high-performance liquid chromatography (HPLC; MenariniHA8140®), and (4) usefulness of POC analyzer for the department of pediatrics.

The POC system for the determination of HbA1c showed good analytical performances, with imprecision values below the reasonable coefficients of variation (CVs) of 3%.[2] At HbA1c levels of 4.9%, 5.6%, and 8.7%, the intra-assay CV on 10 replicates of each HbA1c level was 2.7%, 1.6%, and 1.4%, respectively. The interassay CV, assessed twice a day on 10 consecutive workdays ranged from 1.8% to 2.4%. In 124 routine samples with hemoglobin F <1%, covering a range of 4.6% (27 mmol/mol) to 11.7% (104 mmol/mol), excellent correlation was observed between the HbA1c values with the POC analyzer in comparison with the HPLC method (**Figure 1**). Regrettably, the POC method did not pass the NGSP criteria, with a difference beyond the clinically significant limits of ±7% HbA1c. The analysis of 25 samples with hemoglobin F

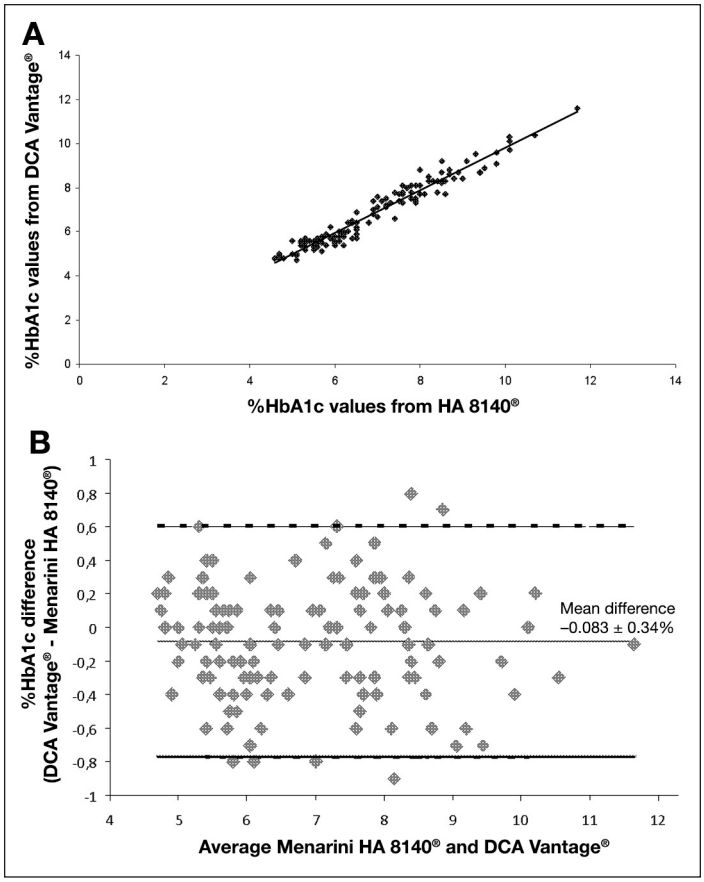

Figure 1. (A) Linear regression of %HbA1c obtained with the HPLC and the POC instrument with $y = 0.9616x + 0.1846$, $r = 0.97$. **(B)** Bland–Altman difference plot. Dotted lines represent the mean ± 1.96 SD of the observed mean difference.

Author Affiliations: Department of Biochemistry, Lapeyronie Hospital, Montpellier, France

Abbreviations: (CV) coefficient of variation, (HbA1c) hemoglobin A1c, (HPLC) high-performance liquid chromatography, (POC) point of care

Keywords: clinical use, hemoglobin A1c, hemoglobin variant, point of care

Corresponding Author: Jean Paul Cristol, M.D., Ph.D., Department of Biochemistry, Hospital Lapeyronie, 191 Avenue du Doyen Gaston Giraud, 34295 Montpellier cédex 5, France; email address *jp-cristol@chu-montpellier.fr*

from 1% to 8.6% brings to light an overestimation (mean difference was 0.44% ± 0.6%) with regard to HPLC method. In addition, in 24 samples with hemoglobin A/S, 7 samples with hemoglobin A/C, and 3 samples with hemoglobin S/C, the correlation with comparative method HPLC did not pass the NGSP criteria, whatever the variant. From a clinical point of view,[3] we observed no clinically significant differences attributable to the presence of hemoglobin C trait for any level, while for hemoglobin S trait, negative clinically bias was found at both evaluation limits of 6% (0.42) and 7% (0.49). This observation was not in agreement with previously published data[4,5] and Siemens on their own studies. This discrepancy is not only due to the presence of variants but also due to the cumulative effect of the gap between technologies and away from the presence of variants. The Kappa coefficient was higher than 0.75, and the strength of agreement could be considered to be good. However, according to the classification in three categories of American Diabetes Association criteria,[2] a total of 14.5% of results disagreed with the category assignment of HPLC, with an underestimation in 11.3% of samples and an overestimation in 3.2% of samples.

According to the answers given by nurses and biologists to a questionnaire, the following are considered to be the greatest benefits for adopting a POC HbA1c assay: fast results obtained in 6 min in real time, the low 1 µl volume of blood required for testing, and the ability for more rapid decision making.

Before adopting a POC methodology, practices are encouraged to review its feasibility in the context of the office routine and also to conduct periodic comparisons of the accuracy of POC test results compared with those from laboratory analysis. Their use should remain marginal and requires taking some precautions, as the standardization is not complete.

Acknowledgment:

The HbA1c reagents used in this study were kindly provided by Siemens, France.

References:

1. Lenters-Westra E, Slingerland RJ. Six of eight hemoglobin A1c point-of-care instruments do not meet the general accepted analytical performance criteria. Clin Chem. 2010;56(1):44–52.
2. Little RR, Lenters-Westra E, Rohlfing CL, Slingerland R. Point-of-care assays for hemoglobin A(1c): is performance adequate? Clin Chem. 2011;57(9):1333–4.
3. American Diabetes Association. Executive summary: standards of medical care in diabetes--2010. Diabetes Care. 2010;33 Suppl 1:S4–S10.
4. NGSP. *http://www.ngsp.org/*.
5. Little RR, Roberts WL. A review of variant hemoglobins interfering with hemoglobin A1c measurement. J Diabetes Sci Technol. 2009;3(3):446–51.