

SHORT COMMUNICATION ΒΡΑΧΕΙΑ ΔΗΜΟΣΙΕΥΣΗ

Comparison of hemoglobin A1C values from two analyzers: A case study

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Σύγκριση των τιμών αιμοσφαιρίνης A1C από δύο αναλυτές: Παρουσίαση μιας περίπτωσης

Περίληψη στο τέλος του άρθρου

Key words: Analyzer, Hemoglobin A1C

Glycated hemoglobin A1C (HbA1C) is an important biomarker used for monitoring patients with diabetes mellitus (DM). It is recommended that this test should be included for patient management at all diabetic clinics.^{1,2} For determination of the level of HbA1C, a clinical chemistry analyzer is to be used. At present, several types of HbA1C analyzers are available, which can lead to problems in the comparison of laboratory results. This article presents a case study which illustrates the problems arising from the comparison of HbA1C values from two analyzers.

CASE STUDY

The author was consulted on a case of poor agreement between the values of HbA1C derived from two analyzers. This specific case presented in the central laboratory of a tertiary private hospital in Bangkok, Thailand. This central laboratory was certified for the ISO15189. The problem was observed when the laboratory implemented a new HbA1C analyzer. The HbA1C analyzer previously used in this laboratory is the Abbott Architect and the newly implemented HbA1C analyzer is the DCA Vantage.

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During implementation of the new analyzer, it was observed that the results from the new analyzer are usually higher than those provided by the old analyzer. Focusing on the quality control exercises conducted on both analyzers, no problem could be identified in the records. A good correlation between the results obtained from the two analyzers could be seen during the primary trial, with a correlation coefficient of to 0.981. However, significantly higher HbA1C values were consistently derived from the new analyzer (fig. 1). Hence, the questions brought for consultation is “what is the exact cause of the poor agreement between the HbA1C results derived from the two analyzers?”, “is there a problem in either HbA1C analyzer?” and “what should be done in this case?”.

DISCUSSION

This is a classical case study in clinical chemistry. The standardization of HbA1C measurement is the topic to be discussed.^{3,4} Sometimes, problematic determination can be seen in clinical practice, a situation which can arise in any laboratories. In this case, the laboratory that faced the problem consulted the author on comparison of the differences in the values of HbA1C derived on blood samples from the same patients using the DCA Vantage and the Abbott Architect analyzers. The hospital was using Architect HbA1C and DCA Vantage HbA1C was proposed



Figure 1. Correlation between levels of hemoglobin A1C (HbA1C) derived from the two analyzers, Abbott Architect (red) and DCA Vantage (blue), based on the analysis of standard controls.

as replacement, following which the head of the laboratory compared the blood of the same patients on both analyzers. The levels of HbA1C derived from the two analyzers were different, as shown in figure 1. Clinicians had been using values of the Architect HbA1C to adjust patient treatment for a long time and consequently felt some confusion. With the significant differences between the HbA1C levels derived from the two analyzers, the question from the head of laboratory was what is to be done for their clinicians to decide which is suitable for use in their DM service for the monitoring and diagnosis of people with DM.

The primary question is whether either HbA1C analyzer gives an incorrect result. Based on the quality control report, it can be seen that neither analyzer gives problematic results, but the problem is the poor agreement between the results from the two analyzers. Based on the evidence, there is no problem of quality of either analyzer in this laboratory. Hence, to the question "what is the cause of the observation in this case?" the answer is the "measurement range" of each analyzer. Focusing on the Architect analyzer, based on the College of American Pathologists 2009 (CAP A and CAP B) GH2 Survey Data, who reported lower HbA1C values compared to the DCA, the CV of Advantage is good. Indeed, focusing on the Architect principle, hemolysate has to be made and the reagent is certified by the National Glycohemoglobin Standardization Program (NGSP)⁵ but not aligned with Diabetes Control and Complications Trial (DCCT)⁶ (hence not acceptable by US recommendations). Hence, its normal range is not in agreement with the guidelines (upper limit: 6). This is in contrast with the case of the DCA, which is in accordance with the guidelines and DCCT aligned (upper limit: 6.5). The problem of DDCT alignment in the interpretation of HbA1C values in clinical practice is very important but is not well known or often considered.⁷

So the answer to the last consulting question is "it depends on the user to select the analyzer for the clinical service." There is no problem with either analyzer. If the laboratory continues to use two analyzers, the interpretation of the HbA1C results needs to be based on the reference measurement range on each laboratory result report, which will be different for the two analyzers. This might cause difficulties in clinical practice for the physician in charge. Hence, it is better to select only one analyzer for the laboratory.

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ΠΕΡΙΛΗΨΗ

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Η γλυκοζυλιωμένη αιμοσφαιρίνη A1C (HbA1C) είναι σημαντικός βιολογικός δείκτης για την παρακολούθηση των διαβητικών. Σήμερα, διατίθενται αρκετοί τύποι αναλυτών της αιμοσφαιρίνης A1C, γεγονός που μπορεί να προκαλέσει σύγχυση κατά τη σύγκριση των αποτελεσμάτων από διαφορετικά εργαστήρια. Το παρόν άρθρο αναφέρεται σε μία περίπτωση και συζητούνται τα αποτελέσματα σύγκρισης των τιμών αιμοσφαιρίνης A1C που προκύπτουν από δύο τύπους αναλυτών.

Λέξεις ευρητηρίου: Αιμοσφαιρίνη A1C, Αναλυτές

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