Comparison of two automated methods for the measurement of glycated hemoglobin HBA1C: ADAMS A1c (ARKRAY) versus Capillarys 2 Flex Piercing® (SEBIA)

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ABSTRACT

Introduction: The aim of this work is to present the results of a comparative study between the determination of glycated hemoglobin (HBA1C) on the ADAMS A1c® (ARKRAY) and Capillarys 2 Flex Piercing® (SEBIA).

Materials and methods: 310 venous blood samples were randomly selected from routine HBA1C tests. The HBA1C assay was performed on ADAMS A1c® (ARKRAY) and Capillarys 2 Flex Piercing® (SEBIA) during the same day. The data obtained were analyzed by the statistical software MedCalc Version 15.1.0.

Results: The results obtained show a good correlation between the 2 methods: the equation of the Passing-Bablok line is of type Y (Capillarys 2 Flex Piercing®) = - 0.550 + 1.119 X (ADAMS A1c) the 95% confidence interval of this slope is - 0.6467 to - 0.4414 with r = 0.982 and p <0.0001. The Bland-Altman plot shows that the average bias between the two methods is in the order of 0.3 and that the difference between the Capillarys and HPLC measurements of Hba1c is in the range of +1.96 to -1.96 and the Deming regression equation Y (Capillarys 2 Flex Piercing®) = -0.3388 + 1.0911 X (ADAMS A1c).

Conclusion: Our study shows a good agreement of HBA1C results between the Capillarys 2 Flex Piercing® (SEBIA) and ADAMS A1c® (ARKRAY). Laboratory work requires professionals to take into account variations in results when changing methods in their routine work by comparing their results on the various methods.

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Abbreviations
HBA1C, Glycated hemoglobin; HPLC, High performance liquid chromatography.

Introduction

The determination of glycated hemoglobin (HBA1C) is a fundamental test for the therapeutic monitoring of patients with type 1 or type 2 diabetes. The determination of HBA1C is a key indicator for the orientation of therapeutic and clinical choices, which requires a higher level of accuracy and precision of the determination method in order to minimize the risk of error in the therapeutic process (1-4). To date, various methods for the determination of HBA1C have been proposed, which have several advantages such as automaticity, specificity and the possibility of identifying other hemoglobin variants (2, 3). These include high performance liquid chromatography (HPLC), which is commonly used and is recognized as an accurate method, and capillary electrophoresis, which has also proven to be an effective method. In order to adequately determine the HBA1C level, the reliability of the method used for the determination should be taken into account (1-4). In principle, different elements should be considered at the time of the assay, including precision, reproducibility and cost effectiveness (2-5). The purpose of this paper is to present the results of a comparative study between the ADAMS A1c® (ARKRAY) and Capillarys 2 Flex Piercing® (SEBIA) method for the determination of glycated hemoglobin (HBA1C).

Materials and Methods

This method comparison study was performed at the Central Laboratory of CHU Mohammed VI of Oujda in December 2019. The study was performed in accordance with the Declaration of Helsinki. 310 venous blood samples from 187 adult women and 113 adult men were randomly selected from our routine HBA1C test requests. Blood was collected in the morning and HBA1C measurement was performed on whole blood. Samples collected in inadequate tubes or insufficient volume samples were excluded from the study. Samples were processed on the following platforms: ADAMS A1c automated system (ARKRAY) which uses high pressure liquid chromatography, and Capillarys 2 Flex Piercing® automated system (SEBIA) which uses capillary electrophoresis.

All results of HBA1C determinations are expressed in mmol/mol and in percent. The data obtained were analyzed by the statistical software MedCalc Version 15.1.0.

Result

The statistical analysis of the results shows a good correlation between the two methods studied: The equation of the Passing-Bablok line (Figure 1) gives:

Y (Capillarys 2 Flex Piercing®) = -0.55+ 1.119 X (ADAMS A1c)

As for the Deming regression equation, it is of the type:

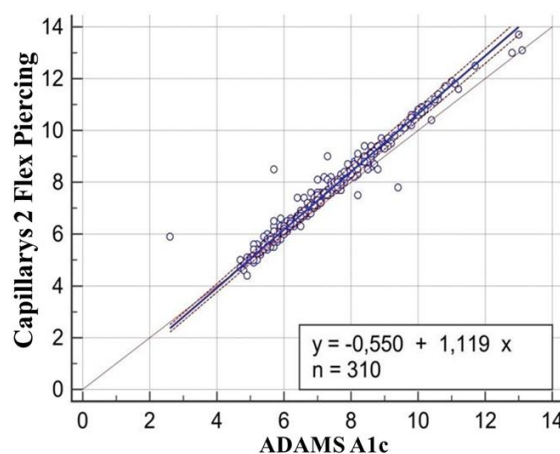**Y (Capillarys 2 Flex Piercing®) = -0.3388 + 1.0911 X (ADAMS A1c)**

Figure 1. Comparison between the two methods using the bablock passing equation.

Of the 300 patients compared, only 08 fell outside the limits of the difference plot. The 95% confidence interval of this slope is -0.6467 to -0.4414 p <0.0001. The Bland-Altman plot shows that the average bias between the two methods is in the range of 0.3 and that the difference between the HBA1C measurements by Capillarys 2 Flex Piercing® and ADAMS A1c is in the range of +1.96 to -1.96.
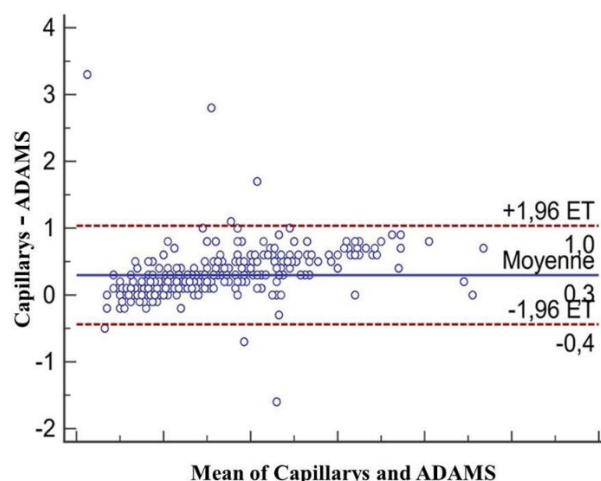

Figure 2.Comparison between the two methods by the Bland-Altman diagram.

Discussion

This comparison of methods shows the possibility of comparing the results obtained by these methods and determining whether there is a bias between them. If there is a discrepancy in results between these methods, it is important to investigate the causes and to inform both prescribers and patients (1-4). In our study, the differences observed indicate results varying in a range of values [-0.5; 0.5], which are therefore close to 0, and which meet the standards (2, 5). The assay method must be certified and quality controlled. Many highly accurate HBA1C assay methods are currently available on the market. The diversity of testing methods is considered to be one of the factors leading to variation in HBA1C values. The international standardization of HBA1C assay methods provides the opportunity to measure HBA1C by interchangeable techniques without affecting the results (3, 4).

The Bland-Altman plot compares the means of the measures with their differences. The average difference value shows that each instrument has a tendency to give lower or higher results than the other. The average result of the differences found is 0.3, which means that the Capillarys 2 Flex Piercing® offers slightly higher values than the ADAMS A1c. However, it is necessary to question the significance of this 0.3 difference. In fact, the reading of the validation limits is based on the clinical-biological context, not on "reference" values (2- 7). It is therefore necessary, for the correct interpretation of the Bland-Altman graph, to take into account the difference considered acceptable between the two instruments (2, 4, 5, 7). Indeed, the acceptable difference between two measurements obtained by two instruments is ± 2 units (1-3). The two methods are in agreement and the measurements obtained are then considered similar or interchangeable. The results therefore showed the transferability between the two methods.

Every medical biology procedure is part of a preventive, diagnostic, prognostic and therapeutic approach (8,9). The responsibility for this act lies with the biologist, who is responsible for all the stages of the pre-analytical, analytical and post-analytical processes, from the prescription stage to the validation of the results and their distribution (7-9). The NF EN ISO 15189 and NF EN ISO/CEI 17025 standards set the general conditions for the quality of medical laboratories (8, 9).

Therefore, and in general, the quality approach is an essential and constant priority for the biologist and all the laboratory staff (9). The central laboratory of the Mohammed VI University Hospital in Oujda is involved in a quality approach including a process of verification of methods according to scope A, and an accreditation plan. This study will allow us to set up the   solid bases for the realization of an accreditation process of the tests used in our laboratory.

Conclusion

Our study shows a good agreement of HBA1C results between the Capillarys 2 Flex Piercing® (SEBIA) and ADAMS A1c® (ARKRAY). Laboratory work requires professionals to take into account variations in results when changing methods in their routine work by comparing their results on the various methods, going through validation testing and developing their own reference values. There are also factors that come into play when interpreting HBA1C results, including its kinetic properties as well as the assay kit, due to the recent trend towards personalized medicine.

Declarations

Conflicts of interest
Not applicable.

Authors' Contributions
The authors acknowledge having actively participated in the work, having read the content of the article and having given their agreement to this content.

Ethics approval:
The study was conducted in accordance with the Declaration of Helsinki.

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