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A Retrospective Assessment of the Agreement between HbA1c Results Obtained using the A1Care Analyser and Those from the Laboratory

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Abstract: **Original Research**

Glycated haemoglobin (HbA1c) is a key marker in the management of diabetic patients, particularly for monitoring blood sugar balance. It is widely used for the diagnosis and management of diabetes. Given the low compliance with laboratory testing frequency and the subsequent delay in treatment modification, point-of-care (POC) HbA1c testing offers an opportunity to improve diabetes management through rapid, actionable test results that can be used to determine treatment effectiveness, make therapeutic adjustments, and ensure that patients are following recommendations. The objective of our study is to evaluate the concordance between point-of-care HbA1c results and laboratory-measured HbA1c values in a hospital-based diabetic population.

Keywords: HbA1c, A1CareTM HbA1c Analyser, Diabetes Management.

INTRODUCTION

Diabetes is a very common condition associated with the development of serious complications, such as cardiovascular or renal disease [1].

HbA1c is used to monitor diabetes and diagnose poor glycaemic control. It is also clearly useful for determining the duration of a recently diagnosed case of hyperglycaemia, within the three-month period of glycaemic exposure that it reflects [2].

Given the low adherence to laboratory testing schedules and, generally, a subsequent delay in adjusting treatment, point-of-care HbA1c testing offers an opportunity to improve diabetes management through a quantitative analysis carried out in a matter of minutes [3].

The aim of our study is to assess the agreement between HbA1c results obtained using two different methods: a system utilising high-performance liquid chromatography (HPLC) variant II in our laboratory and the A1Care analyser in hospitalised diabetic patients [4, 5].

Materials and Methods

This was a retrospective observational study conducted in the Department of Endocrinology, Diabetology and Metabolic Diseases at the Avicenne Military Hospital in

Marrakesh (Morocco) over a two-month period in 2025, involving 30 patients with diabetes.

The sample was drawn from thirty hospitalised diabetic patients who consented to participate in the study and from whom blood was drawn into EDTA-containing tubes. The samples were analysed immediately.

For each sample, HbA1c measurements were carried out in parallel on two automated systems based on different principles. These were the laboratory system using high-performance liquid chromatography (variant II) and the A1Care analyser.

About the A1Care™ HbA1C analyser [6, 7]:

The A1Care™ analyser uses fresh whole blood – either capillary or venous – as the sample type. It specifically measures glycated haemoglobin, with a measurement range of 4 to 15 per cent (i.e. 20 to 140 mmol/mol). The sample volume required for each test is 2.5 µl, and the time taken to obtain a result is 4 minutes and 20 seconds. The device operates within a temperature range of 10 to 32 °C; its estimated shelf life is 12 months, and it can be stored at temperatures ranging from 1 to 30 °C.

NGSP (National Glycohaemoglobin Standardisation Programme) certification applies solely to the HbA1c test. The ACR (albumin-to-creatinine ratio) test is not certified by the NGSP, as this organisation focuses specifically on the standardisation of HbA1c measurements.

The A1Care™ analyser is also certified by the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine), further reinforcing the reliability of its measurements.

Data were collected from the medical records of hospitalised patients, which systematically recorded demographic, clinical and laboratory data. Data entry and statistical analysis were carried out using Excel.

RESULTS AND DISCUSSION

1-RESULTS

a- Description of the study population (Table I):

The mean age in our study was 50.17 years ± 20.77 years. The male-to-female ratio was 5. Eight patients (26.66%) had type 1diabetes and 22 patients (73.33%) had type 2 diabetes.

In terms of medical history, 10 patients (33.33%) had hypertension, 4 (13.33%) were obese, 5 (16.66%) had dyslipidaemia and 11 (36.66%) were smokers.

Nine patients (30 per cent) reported no specific medical history. With regard to degenerative complications, 5 patients (16.66%) had diabetic retinopathy, 4 (13.33%) had diabetic nephropathy, 4 (13.33%) had coronary artery disease and 3 (10%) had peripheral arterial disease.

The mean HbA1c value measured in the laboratory was 10.17 ± 2.63%. The value measured by the A1Care analyser was 9.79 ± 2.66%.

Table 1: Description of the study population

Variable	**(N = 30)**
Age (years)	Mean ± SD: 50.17 ± 20.77
Gender	Men: 25 (83.33%) Women: 5 (16.67%)
Type of diabetes	Type 1: 8 (26.66%) Type 2: 22 (73.33%)
Medical history	Hypertension: 10 (33.33%) Obesity: 4 (13.33%) Dyslipidaemia: 5 (16.66%) Smoking: 11 (36.66%) No history: 9 (30%)
Complications	Diabetic retinopathy: 5 (16.66%) Diabetic nephropathy: 4 (13.33%) Coronary artery disease: 4 (13.33%) Peripheral arterial disease: 3 (10%)
Lab HbA1c	Mean ± SD: 10.17 ± 2.63
HbA1c A1Care (%)	Mean ± SD: 9.79 ± 2.66

SD: Standard deviation

b- Analysis of HbA1c variation:

The mean HbA1c measured in the laboratory was 10.17 ± 2.63 %, whilst that measured by the A1Care analyser was 9.79 ± 2.66 %. The difference in means is 0.38 %, which represents a slight underestimation of HbA1c by the A1Care analyser compared with the laboratory method.

The standard deviations observed for the two methods were very similar (2.63 % for the laboratory method versus 2.66 % for the A1Care analyser), suggesting a comparable degree of variation in the measured values.

A simple linear regression was performed to model the variation in HbA1c measured by the A1Care analyser as a function of that measured by the laboratory.

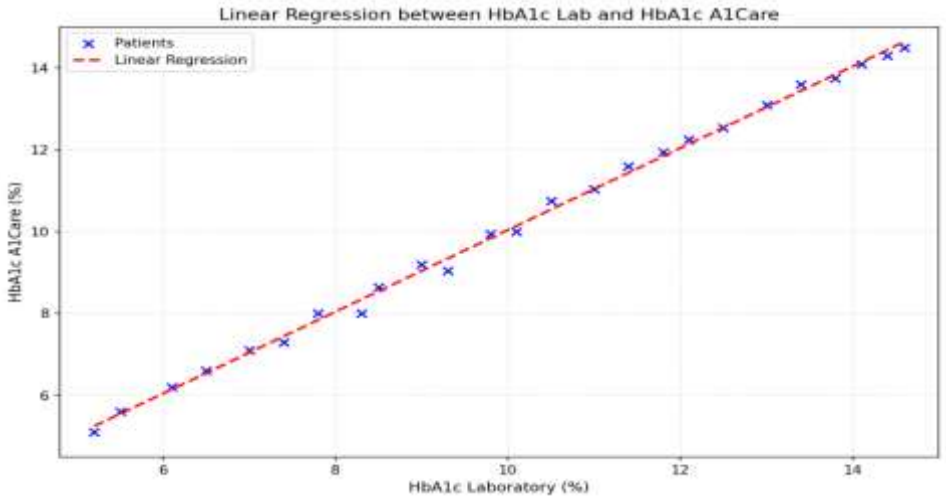

Figure 1: Plot of the simple linear regression line between HbA1c measured by the A1Care analyser (y-axis) and that measured by the reference laboratory (x-axis)

It indicates a strong linear correlation and good agreement between the two methods. This relationship was highly significant ($p < 0.0001$), with a coefficient of determination R^2 of 0.965 and a correlation coefficient of 0.974964.

2-DISCUSSION

The main objective of our study was to assess the agreement between HbA1c values obtained using the A1Care analyser and those from the reference laboratory, using an analytical approach based on linear regression. This method allows us, beyond a simple correlation, to analyse the quantitative relationship between two measurement techniques and to identify systematic biases [8].

Our results show good agreement between the two methods, illustrated by a linear regression line with a slope close to 1, indicating a consistent proximity between the measurements. These data suggest that the A1Care analyser can be used in clinical practice to provide reliable HbA1c results, with an acceptable degree of precision.

This finding is consistent with the results of previous studies evaluating other portable devices, notably the DCA Vantage Analyser (Siemens) and the Afinion AS100 Analyser (Abbott), which also demonstrated good agreement with reference methods [9, 10].

A more recent study reported that correctly calibrated point-of-care devices could be successfully integrated into diabetes management protocols, particularly in resource-limited settings or primary care settings [11].

Five cross-sectional studies [1, 12, 13] compared the correlation between point-of-care HbA1c testing and laboratory-based HbA1c measurement.

The following table summarises the characteristics of these studies and those of our study (Table 2).

Table 2:

Author, Year Study	Study sample, n	Pays	POC HbA1c device	Reference test	Time between POC HbA1c and laboratory HbA1c tests
Arrendale *et al*., 2008 [12]	70	USA	A1c Now $^{+}$	Standard laboratory HbA1c assays	Within 7 days
Leca *et al*., 2012 [15]	100	France	DCA Vantage	Tosch high-performance liquid chromatography	Within 2 hours
Leal *et al*., 2009 [16]	47	USA	A1c Now $^{+}$	Standard laboratory HbA1c assays	Within 4 days
Martin *et al*., 2010 [17]	100	France	In2it	High-performance liquid chromatography variant II	Within 6 hours
Yeo *et al*., 2009 [13]	80	Singapour	In2it	Cobas c501 improved competitive latex immuno-turbidimetric assay	Within 5 to 15 minutes
E. Niyogushima *et al*., 2025 [18]	30	Maroc	A1 Care analyser	High-performance liquid chromatography variant II	Within 15 to 60 minutes

The devices most frequently studied were the A1cNow+, the DCA Vantage and the In2it. Studies by Arrendale *et al*., (2008) [12], Leal *et al*., (2009) [16] and Leca *et al*., (2012) [15] demonstrated a good correlation between point-of-care HbA1c test results and laboratory methods, with correlation coefficients ranging from 0.893 to 0.987, indicating a high degree of agreement. These devices are validated by the NGSP, further reinforcing the reliability of the results obtained.

Our study, included in this table, is notable for its evaluation of a device that has received little attention in the literature: the A1Care analyser.

CONCLUSION

The HbA1c test is an essential part of diabetes management and is a considerable asset in the screening and diagnosis of diabetes. The drawback of laboratory-based HbA1c tests is the delay in receiving results due to the time taken to produce the reports.

Our results support the view that A1Care represents a promising option in diabetes management, particularly due to the speed with which results are delivered, thereby facilitating immediate clinical decision-making during consultations or in therapeutic education settings. Its use could also contribute to improved patient adherence to blood glucose monitoring, an essential factor in achieving the blood glucose targets recommended by the American Diabetes Association [14].

A comparative analysis of the HbA1c results obtained using the A1Care analyser and those from the reference laboratory shows good agreement between the two methods, as validated by linear regression. These results suggest that the A1Care analyser is a reliable tool for assessing glycaemic control, particularly in clinical settings where rapid results are required.

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