

Comparison of Two Rapid Methods for Determining A1C

Abstract

An immediate hemoglobin A_{1c} (A1C) result is a valuable tool for physicians in their routine management of patients with diabetes mellitus. A comparison study evaluated A1C results using the boronate affinity method of the Cholestech GDX™ System and the immunoassay method of the Bayer DCA 2000®. 56 patient blood samples were collected in EDTA tubes and were tested on both methodologies within 24 hours. The GDX and Bayer DCA 2000 A1C values were very highly correlated ($r = 0.96$). The two systems are NGSP-certified and CLIA-waived, enabling rapid, accurate assessment of A1C levels in diabetic patients.

Introduction

Routine determination of A1C is now the standard of care for evaluating the control of diabetes. This measurement provides valuable information, necessary for determining the effectiveness of the therapeutic plan and for facilitating timely change in the therapeutic regimen.^(1,2)

The Cholestech GDX™ is a CLIA-waived A1C testing system for measuring A1C in less than five minutes using a drop of blood from a fingerstick. The GDX System provides the health professional with immediate information on the long-term glucose control of their patients, allowing them to implement management changes. Delayed patient feedback could lead to decreased patient compliance and delayed adjustment of hypoglycemic regimens.

A study was conducted to evaluate the two rapid A1C testing methods.

Method

The study was conducted with type 1 and type 2 diabetic patients that routinely attended Wrexham Maelor Hospital (Wrexham, UK). Samples were drawn and stored in EDTA tubes at 2-8°C and used within 24 hours. The samples were then analyzed using the GDX and DCA 2000. The A1C results from both the GDX and the DCA 2000 were compared using Deming linear regression.

Results

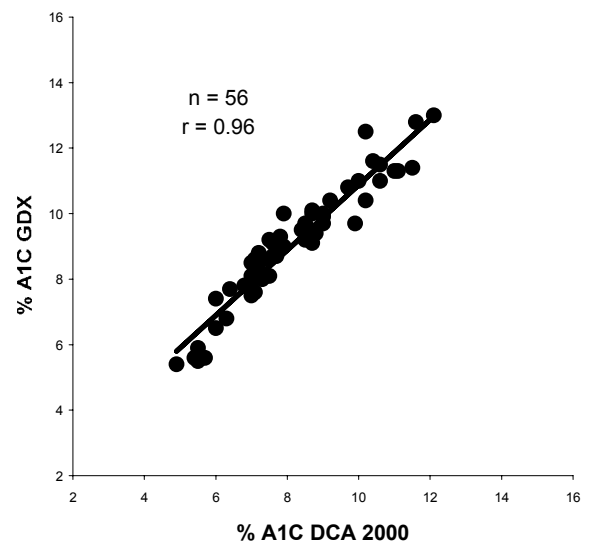
The GDX and DCA 2000 were very highly correlated ($r = 0.96$) and yielded a linear regression of: $y = 1.04x + 0.5$ (Figure).

References

1. Ferenczi A, Reddy K, Lorber DL. Effect of immediate hemoglobin A1c results on treatment decisions in office practice. *Endocr Pract* 2001; 7(2):85-88.
2. Cagliero E, Levina EV, Nathan DM. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. *Diabetes Care* 1999; 22(11):1785-1789.

Figure.

Method Comparison: GDX and the DCA 2000



Conclusion

In this study, the GDX and DCA 2000 assay methods were found to be substantially equivalent. The NGSP-certified, CLIA-waived GDX System provides an A1C result in less than 5 minutes. Rapid testing for glycemic control allows for immediate changes in patient management at the time of consultation.