

A Comparison of POCT and Laboratory Boronate Affinity Methodologies for HbA1c in Diabetic Patients

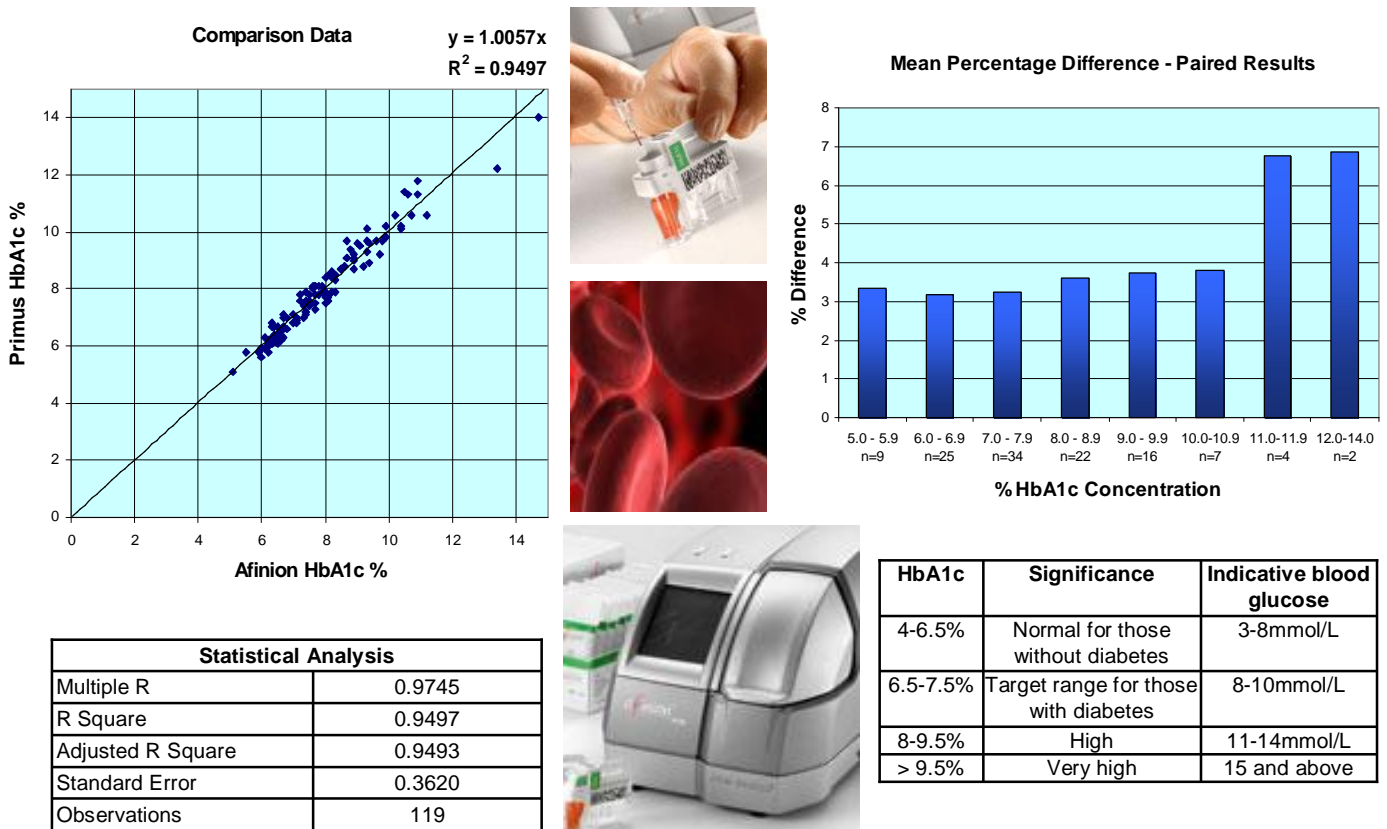
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Introduction

The fraction of haemoglobin that is bound to glucose - HbA1c is a widely accepted indicator of glycaemic control throughout the average turnover time of a patient's red cell population. National guidelines for the monitoring of specific diabetic sub-groups, and increased diagnosis of Type 2 diabetes within the community has significantly increased the demand for HbA1c analysis. Individuals may be seen in different community and hospital locations and therefore a good correlation between the serial measurements is preferable for consistent interpretation and treatment strategies. The Afinion was selected following evaluation for use in the hospital diabetic clinic, and recommended for use in local primary care. This study was conducted to examine and confirm the analyser performance when used in the daily clinic environment compared to the routine automated HPLC results reported by the laboratory.

Methods

The majority of clinic samples are taken as fingerprick specimens collected into the integral capillary of an Afinion cartridge, however if patient venepuncture was required (cholesterol monitoring) an EDTA blood sample was also taken and analysed immediately on the Afinion for HbA1c by nursing staff. This sample was then stored at room temperature and analysed by BMS staff within the main hospital laboratory the following day (maximum 72 hours) using an automated boronate affinity HPLC system. Analysis methods are DCCT-aligned.



Results and Discussion

The paired results (n=119) were obtained over a 33 week period, during which time a total of 832 samples were analysed by the Afinion. Analysis for both the Afinion and laboratory based HPLC method varied with respect to 'consumable' lot numbers, and was completed by a range of operators. HbA1c results up to 11% showed excellent correlation, with values between 11% and 12% exhibiting slightly increased scatter. Data above 12% was very limited, but in this study indicated a positive bias within the Afinion results.

For the duration of the study period the Afinion analyser had no unplanned 'down' time. The cartridge analysis failure rate was 2.7%. Diabetic clinic staff followed a checklist start-up procedure and results were recorded onto daily worksheets. The data recall function on the Afinion was later used to verify values before entry into the patient record. The reported measuring range of the Afinion is up to 15% HbA1c and as data was limited in this range further study of patients with laboratory results of 12-15% HbA1c is planned.

Of the 832 Afinion HbA1c results obtained in the study period 92.9% were below 11% and 97.2% were below 12%. For the purposes of diabetic treatment management strong correlation up to 12% affords appropriate result accuracy for the majority of individuals. Service streamlining by performing rapid fingerprick HbA1c analysis during the pre-checks prior to Consultant appointment improves the patient experience most notably in elderly and paediatric clinic groups. The reduction in associated phlebotomy visits and the clerical support time required to ensure result availability can offset the increased cost per test.

Acknowledgements

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