

Point of Care Testing in the Community – HbA1c Testing Pilot with Heart of Birmingham PCT

Personnel involved

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Introduction

A pilot study into HbA1c Point of Care testing (POCT) in the community was conducted in November and December 2008 at the Laurie Pike Health Centre in conjunction with the Clinical biochemistry department at City Hospital. The aim was to assess the feasibility and value of providing HbA1c results for patients that were immediately accessible to the General Practitioner during attendance at a diabetic clinic. A key aim was to expand the pilot to include more medical centres in HOB PCT if the initial study proved a success. Two POCT devices for HbA1c analysis were compared during the trial to identify the appropriate machine for use in our model of a HbA1c testing service (see appendix).

Methods

Patients underwent their usual pre-assessment prior to their consultation. At the start of the assessment, EDTA blood samples were taken and handed to a member of the Clinical Biochemistry Department for immediate analysis.

Two HbA1c analysers were assessed during the pilot study, the Siemens DCA Vantage and the Axis-Shield Afinion. Results were generated from both analysers, but only the DCA result was given out to the Healthcare assistants, as this machine was deemed to be a more established analyser in the field of HbA1c testing and had been previously used by the surgery.

After the clinic, all samples were re-evaluated on the laboratory TOSOH G7 analyser. These laboratory results were also made available to the healthcare centre.

The results from 50 samples were recorded and subjected to statistical analysis to judge their accuracy, repeatability and agreement with the laboratory method. Inter- and intra-batch coefficients of variance (CVs) were calculated for both analysers to assess their consistency. The HbA1c results from each analyser were plotted against the TOSOH G7 results and the R² value calculated. Attention was also paid to how each analyser handled samples from patients with haemoglobin variants.

The time taken by each analyser to generate results, the potential for user error, running costs and the overall suitability as a point of care analyser that has to be transported for use in different clinics were assessed. The potential for running albumin/creatinine ratios (ACRs) as an additional test provided by the service was considered.

Results

Statistical analysis

Both methods showed excellent consistency, giving good inter-batch and intra-batch CVs. Both analysers also compared well to the laboratory method (Table 1), although both methods give values that are often slightly lower than the TOSOH G7 results (Table 1; Fig.1). This is due to a slight positive bias in the laboratory system compared to the other systems caused by differences in the HbA1c method employed.

Table 1: Statistical analysis of the HbA1c results from the Afinion and the DCA Vantage

Analyser	CV (intra-batch)	CV (inter-batch)	R ² ‡
Afinion	0.9 %	2.0 %	0.96
DCA Vantage	1.59 %	2.0 %	0.95

‡ From a comparison with the TOSOH G7

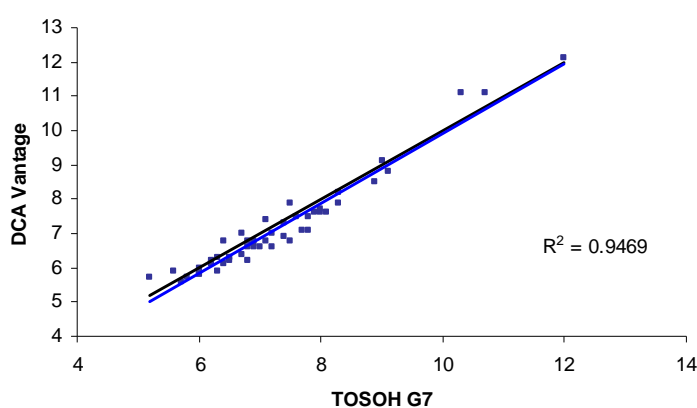


Figure 1(a): DCA Vantage HbA1c results plotted against the TOSOH G7 results. The R² value for the DCA results compared with the TOSOH G7 results is shown on the graph

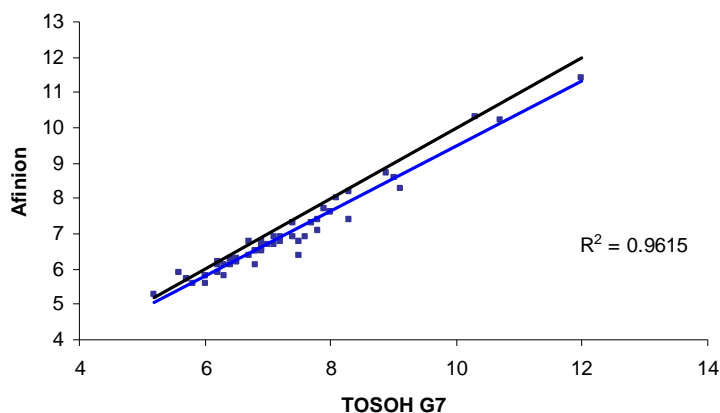


Figure 1(b): The Afinion HbA1c results plotted against the TOSOH G7 results. The R^2 value for the Afinion results compared with the TOSOH G7 results is shown on the graph.

Functionality of the analysers

Afinion: Test cassettes are individually foil wrapped and the capillary for sampling provided ready for use in the cassette. All information required for calibration (i.e. batch number etc) and testing is included in the bar code on the cassette which is read when the cassette is introduced into the machine. There is no need to swipe calibration cards or the cassette prior to commencing the test. This may help to reduce user error in a system that has to be transported along with its reagents to different clinics.

Results are obtained within 3 minutes 15 seconds (1) and are displayed on the analyser screen. There is no onboard printer to provide a direct hard copy of the results but there is the potential to connect a mini-printer via its USB port. Results that are beyond the Afinion's detection limits (<4 % and >15%) are indicated by an information message. Data can be transferred to either HIS or LIS systems.

The Afinion is the smaller of the two machines and therefore easy to transport but would benefit from a dedicated bag for keeping it protected during transport and whilst in storage in the laboratory.

The Afinion is quite sensitive to temperature and will not complete a test if its temperature is too low, thereby not giving out erroneous results. This means that care must be taken to ensure that the machine is fully warmed up before use to avoid wasting cartridges.

DCA Vantage: Test cartridges are also individually foil wrapped, but the capillary sampler is provided separately. The capillaries are quite susceptible to breaking but one spare is provided per box. Calibration cards are provided with each box of cartridges and also to register a control sample. These must be swiped before the box contents/control is used. The analyser can only store data from three calibration cards at once therefore care must be taken to ensure that less than three boxes of reagents are in use at any one time. The cartridges are swiped before placing them in the analyser and removing the

tag from the cartridge. The increased number of user steps may increase the potential for the generation of user error.

Test results are obtained within 6 mins (2) which is considerably slower than the Afinion. This was sometimes an issue when the clinic was busy and there was a number of samples waiting to be analysed, but was generally acceptable. The onboard printer is useful to provide a hard copy of the results plus the patients' identifiers, without the need for separate equipment. Results include a '+' to indicate when they are high, and a message displayed when results were above or below detection limits (< 2.5 % and > 14 %). Data can be downloaded to an excel spreadsheet or a data management system.

The DCA is the larger of the two machines but a padded bag for its transport was provided.

No problem was encountered with rejection of a cartridge once the test has started due to the analyser temperature being too low, as a message appears once the machine is ready to use.

Variant Haemoglobin

The presence of variant haemoglobins in a sample has the potential to interfere with the results of HbA1c analysis (3). Affinity based methods such as those used by the DCA and the Afinion analysers (immuno- and boronate-affinity respectively) are generally less susceptible to the affects of variants. Out of the 50 patients whose samples were used in this study, 7 (14%) were found to be heterozygous for a variant haemoglobin. Both analysers appeared unaffected and gave results in good agreement with the TOSOH G7. A sample that was received in the laboratory and gave erroneously low results on the TOSOH G7 due to the effects of a particular variant type was also handled well by both analysers. It should be noted that the size of the pilot study limits the scope of this part of the investigation.

Efficiency of the service

The turn-around times given by both analysers were generally sufficiently short to enable a result to be available before the patient went in for their consultation. However, the longer time taken by the DCA Vantage to generate a result was occasionally found to be a limiting factor, especially when there were a number of samples to be analysed.

ACR analysis

Albumin creatinine ratios (ACRs) were not run on the analysers during the clinics, but their agreement with the laboratory method and their consistency was evaluated in the laboratory. Both analysers performed well. The DCA again takes the longest time to run the samples, which may well make it impractical to use if the decision is made to provide ACR results during the clinics. The DCA test procedure is more complicated than that of the Afinion, with a number of user steps required. However, it is yet to be determined

whether ACR testing is a service that would be clinically advantageous in a point of care setting.

Discussion

The service was well received as it provided results that could be acted upon by the practitioner without the need for calling the patient in for a second consultation. There are key advantages to this 2010 model of patient care, including meeting a range of clinical governance issues. This model also avoids putting additional pressure on healthcare assistants to analyse results during patient pre-assessments in a busy diabetic clinic. The study was extended into December and will be expanded to include three healthcare centres in 2009.

Both analysers give reliable results that compare well with the laboratory service for HbA1c. The simplicity of the Afinion and its shorter test time may make it more practical to use during a busy clinic, and provides the flexibility to add on ACR testing to the service. The DCA Vantage requires more individual pieces of equipment (calibration cards, capillaries, control cards) that have to be transported with the machine and used correctly. This may not be ideal for a system that is required to be moved to multiple locations.

Acknowledgements

Kirstyn Nicholas, Siemens

Sue Younghusband, Axis Shield

References

- (1) Axis-Shield Afinion product information
- (2) Seimens DCA product information
- (3) 'Haemoglobin A1c in the diagnosis and monitoring of Diabetes Mellitus', E. S. Kilpatrick; J Clin Path 2008; 61: 977-982

Appendix

Key features of our 2010 Style Service Model:

- The laboratory will offer expertise in analysis including the provision of staff and equipment which goes out to different clinics during the week.
- There will only be the need for one set of analytical platforms as these will be moved around to the different locations that will be offering POCT.
- Close contact between clinical and laboratory staff including overall management of this service will be put in place. We will very much use this as a pilot of a 2010 partnership style of service.

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