Multicenter Evaluation of Tosoh Glycohemoglobin Analyzer

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Background: We describe an Anglo-French evaluation of a new analyzer.

Methods: The Tosoh HLC-723 GHb V, A1c2.2 glycohemoglobin analyzer is an HPLC instrument with primary blood tube sampling, bar-code reading, cap piercing, and the ability to chromatographically separate labile hemoglobin A1c (HbA1c). We evaluated two analytical protocols, 2.2 and 3.0 min, and compared results for blood samples collected from diabetic and nondiabetic subjects with those obtained with Bio-Rad Diamat and Variant analyzers.

Results: Within- and between batch-precision (CVs) was <2% with linearity to at least 15.9% HbA1c. Although some hemoglobinopathies were detected in the 2.2-min chromatography, clearer evidence of abnormality was visible in the 3.0-min version. Comparison with established methods showed good correlation ($r = 0.993$; $n = 316$ with Diamat; and $r = 0.995$; $n = 133$ with Variant) but highlighted calibration differences.

Conclusions: The problems of manual blood sample preparation, labile HbA1c, and carbamylated hemoglobin interference associated with the older instruments have been eliminated in the new Tosoh analyzer. The 3.0-min protocol is preferred for routine use.

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Glycohemoglobin measurement provides the most important medium- to long-term marker of time-averaged glycemic status. Its relationship to likely clinical outcome in diabetes mellitus has now been so convincingly demonstrated for both type I and type II subjects in major, lengthy clinical trials (1, 2) that its already widespread use will undoubtedly increase further. An extension of the role of this measurement from monitoring to the diagnosis of diabetes is also favored by some (3), thereby creating the possibility of even greater demand for this analysis.

Various methods have been used for the measurement of glycohemoglobins (4). Analytical goals have included greater practical convenience with automated systems and greater specificity of measurement of the N-terminal valine glycation product [hemoglobin A1c (HbA1c)]. The precision of HPLC methods has favored their use, and the column technology has been refined to achieve shorter analysis times. Along with this have come compromises in the chromatographic quality and resolution. For many HPLC systems using the ion-exchange principle, it has been necessary to remove the labile HbA1c Schiff base intermediate before chromatography, thereby adding to the labor involved, particularly if this constitutes an off-system analytical step.

We have evaluated the newest of the HPLC ion-exchange systems, the Tosoh HLC-723 GHb V, A1c2.2, in an Anglo-French collaboration. The system is offered with two different analysis protocols thought to be suitable for general diabetic monitoring. The principal novel feature of the analyzer is its quantitative separation of the labile glycohemoglobin on column. Our evaluations were performed according to the Valtec protocol (5) in France and local evaluation procedures in the United Kingdom.

Materials and Methods

Instrument
The Tosoh HLC-723 GHb V, A1c2.2 is a small (45 cm high, 55 cm wide, 57 cm deep), fully automated bench top analyzer (Tosoh). The system requires an external power supply, with liquid waste being optionally collected into a bottle or routed to a drain. Control and programming are via a touch screen. An internal floppy disk drive is used.

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for system software loading and sample data storage. Chromatograms are printed on a thermal printer. A 1.44-Mb disk can store 290 full chromatograms with associated data or up to 26 400 sets of sample results alone.

Samples are placed in Sysmex® racks, which can be continuously fed onto the sample loader as processing takes place. Blood sampling is possible from either primary tubes with optional cap piercing or from small dilution vials, with combinations acceptable in a rack. A bar-code reader handles common code configurations for positive sample identification.

COLUMNS AND REAGENTS
Separation of hemoglobin fractions is achieved by injection of 3 μL of automatically diluted hemolyzed sample through a prefilter onto a nonporous glycidyl methacrylate-ethylene glycol methacrylate copolymer cation-exchange column maintained at 25 °C in an aluminum block oven. The minimum expected lives of the prefilter and column are 500 and 2500 injections, respectively. The hemolysis/wash reagent is an aqueous EDTA solution containing Triton X-100. Fractions are eluted from the TSKgel® Glyco HSi column by a three-step increasing ionic strength buffered succinic acid gradient. The three component buffers, which undergo continuous vacuum degassing, are contained in foil pouches located on top of the instrument.

A novel feature of the Tosoh HPLC system is that the labile HbA1c (L-A1c) fraction does not have to be removed by preanalysis degradation or on-column chemical or other means because it is well resolved from the stable HbA1c (S-A1c) and other Hb fractions of interest (Fig. 1) as a result of the interaction of properties of the resin, buffers, and gradient used. The separated fractions are monitored with a diode detector system at 415 and 510 nm.

OPERATION
A two-point calibration may be performed after every power-up or only when specifically requested. Alternatively, the instrument may be externally calibrated by input of factors to allow alignment with Diabetes Control and Complications Trial (DCCT) calibrators for example. Recalibration is not required from the standby state. The calibration parameters are printed after the initial calibration and on all subsequent sample chromatograms.

Calculation of results is based on the ratio of the S-A1c fraction chromatographic area to that of the total HbA, which is automatically adjusted using the calibration equation. The percentages of total HbA1 and S-A1c are printed on the report, which may include other information if desired, e.g., full sample identification and calibration and peak information along with the chromatogram.

A 2.2-min chromatographic run time provides basic rapid separation, whereas a 3.0-min version allows better detection of hemoglobin variants. Both protocols have a lag time of 4.4 min after the initiation of processing, with the first result available in 6.6 min for the 2.2-min protocol and 7.4 min for the 3.0-min protocol. After a batch of analyses, the instrument enters a 10–15 min wash phase, which can be interrupted. The instrument then returns to stand-by for up to 3 h before automatic power-off. Additional samples may be analyzed at any time in the stand-by period without a requirement for further calibration.

COMPARISON INSTRUMENTS
The Tosoh analyzer was compared with two others used routinely in the authors’ laboratories. In France, a Bio-Rad Diamat HbA1c analyzer (Bio-Rad Laboratories) was operated according to the manufacturer’s instructions. Manually diluted samples were preincubated for 30 min at

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**GLYCOHEMOGLOBIN REPORT**

DIABETES CENTRE
NO. 009 00032 1998/11/30 11:08
SAMPLE ID 0267605
CALIB Y = 1.1448X + 0.2973

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TOTAL AREA 1842.68

SA1C 5.3 TOTAL A1 6.3

Fig. 1. Chromatogram for Tosoh 3.0-min protocol with full associated data printout showing a nondiabetic profile.
The shaded peak indicates S-A1c; the separated L-A1c is shown with an arrow, and the largest peak is HbA0.
37 °C (off-system) to remove the labile fraction. Calibration was by means of Bio-Rad materials with locally accepted values that were not confirmed as DCCT aligned. In the UK laboratory, a Bio-Rad Variant HbA1c analyzer (Bio-Rad Laboratories) was operated according to Bio-Rad protocols but with manually diluted samples preincubated off-system for 30 min at room temperature to remove the L-A1c fraction. Calibrators supplied by Bio-Rad were used, and this analyzer had periodic verification of calibration against a DCCT Secondary Reference Laboratory in the University of Minnesota, Minneapolis, MN.

EVALUATION SAMPLES
Venous blood samples were collected into EDTA Vacutainer Tubes (Becton Dickinson) in both the United Kingdom and France. In addition, outpatient samples in France were collected into Bio-Rad sample preparation vials (cat. no. 196-1026) containing aqueous EDTA and potassium cyanide. Blood specimens were obtained from patients whose diabetic control was being assessed routinely and were used in this study according to local ethics guidelines. These were used for comparison with established local methods.

Samples for assessment of the reference interval were collected from 40 nondiabetic, nonuremic, nonobese subjects (15 men and 25 women, ages 22–55 years) with no known diseases.

Automatic 1:250 dilutions of all blood samples were prepared by the Tosoh analyzer and all manual dilutions were made in hemolysis/wash reagent according to the manufacturer’s instructions.

Quality-control materials used throughout the evaluations were Lyphochek Diabetes Control Levels 1 and 2 (Bio-Rad Laboratories).

LABILE FRACTION
Because the labile fraction is not removed but is separated as a distinct peak on the column, the following steps were taken to confirm the L-A1c peak characteristics.

Glucose incubation. To confirm the position and effective separation of the labile fraction peak, buffered saline-washed red blood cells were incubated with glucose solutions to increase this fraction and were analyzed at intermediate time points for 6 h. Two samples of washed red blood cells with HbA1c values of 5.1% and 10.1%, respectively, were incubated with glucose solutions to achieve final glucose concentrations of 10, 20, and 50 mmol/L. These suspensions were incubated at 37 °C for 6 h. Aliquots were removed after 15, 30, 60, 120, 240, and 360 min and immediately diluted in hemolysis/wash reagent to prevent further glycation.

Chemical removal. To investigate the possible multicomponent nature of the L-A1c peak, chemical elimination of the labile fraction with a Bio-Rad EDTA-cyanide preparation was performed. Twelve samples collected in Bio-Rad sample preparation vials were incubated with Bio-Rad borate buffer (cat. no. 196-1052) for 30 min at 37 °C to destroy L-A1c. The samples were analyzed from the primary blood tube and also from the prepared sample before and after incubation.

Storage effect. Consistency of the S-A1c and L-A1c fractions over time was investigated by intermittent analysis of blood samples over 21 days. Samples were stored in primary tubes at 4 °C throughout.

SAMPLE CARRYOVER
Carryover between blood samples with high and low HbA1c concentrations was checked using both the method of Broughton et al. (6) and as recommended in the Valtec protocol (5). The Valtec procedure involved analysis of 10 low-concentration samples, then 10 high-concentration samples, and then these 20 samples intermixed. The results of both analyses may then examined for interactions. The method of Broughton et al. involved processing triplets of low- and high-concentration samples sequentially and examining the first and third results of each triplet for systematic deviation. The method of Broughton et al. was used for the 3.0-min protocol, and the Valtec procedure for the 2.2-min protocol, both with cap piercing.

SAMPLE SEDIMENTATION
When a cold start and a full 90-place sample loader are used, the maximum time to final sampling is 272.4 min for the 3.0-min protocol. We therefore examined the stability of results obtained on primary blood samples with HbA1c concentrations of 5.5%, 7.2%, and 10.3%, which were allowed to stand unmixed for up to 5 h. They were presented to the analyzer hourly along with a second aliquot of each sample in which the cells were resuspended immediately before analysis.

HEMOGLOBIN LOAD
The manufacturer’s claim is that the optimized total chromatographic area should be between 1000 and 4000 units. We therefore investigated the effect of varying hemoglobin load on chromatographic quantification. For the 2.2-min protocol, increasing volumes of blood were diluted in a fixed volume of diluent to give a range of final sample dilution ratios from 1:1000 to 1:50. For the 3.0-min protocol, a similar range of dilution ratios was prepared by taking a blood sample and manually diluting decreasing volumes of the freshly mixed sample in hemolysis/wash reagent.

HEMOLYSATE STABILITY
Blood samples representing various levels of diabetic control were manually diluted and then analyzed repetitively over a period of 7 h, standing at room temperature in the intervening periods. Because it is sometimes advan-
tageous to collect outpatient samples directly from a finger puncture into hemolysis/wash reagent, the effect of delayed analysis was also investigated. Samples collected in this manner were stored at room temperature and at 4 °C for 7 days and analyzed daily.

**Assessment of Interferences**

**Lipemia.** The potential interference of lipemia was investigated by overloading samples of a pooled blood having an HbA1c concentration of 5% with saline-diluted Intralipid solution (Kabivitrum SA). The volumes of Intralipid added augmented the basal triglyceride concentration by 2.0, 3.0, 4.6, 5.0, and 7.0 mmol/L. Analysis of the samples was carried out immediately after preparation.

**Bilirubin.** Dilutions of a bilirubin solution (cat. no. B4126; Sigma) were mixed with a pooled blood that had an HbA1c concentration of 10% to obtain six final concentrations of bilirubin ranging from 25 to 500 μmol/L. Measurement of HbA1c was performed immediately after preparation.

**Carbamylation.** A range of sodium cyanate solutions up to 10 mmol/L were mixed with a pooled blood that had an HbA1c concentration of 5%. The samples were incubated for 1 h at 37 °C to achieve in vitro carbamylation of the hemoglobin before analysis on the Tosoh 2.2-min protocol and on the Diamat.

**Identification of Hemoglobin Variants.** Variant hemoglobins were identified by means of electrophoresis at acid and alkaline pH with further investigation using either standard hematological or molecular biology techniques as appropriate.

**Results**

**Within- and Between-Run Imprecision**

Within-run imprecision was determined at three concentrations, using pooled blood from diabetic and nondiabetic subjects for the 2.2-min protocol and bloods from individual patients for the 3.0-min protocol. Between-run imprecision was obtained for both protocols using quality-control materials that were analyzed over 3-week periods with single lots of reagents and columns. The data are presented in Table 1. For both protocols, within-run CVs were generally <1% and <2% for between-run performance.

**Linearity**

This was assessed by comparing expected and observed analytical values using results from proportional mixtures of high and low HbA1c samples. For the 2.2-min protocol, samples were prepared by combining proportions of undiluted blood containing 4.7% and 15.9% HbA1c before preparation of the hemolysates. For the 3.0-min protocol, samples containing 5.1% and 14.0% HbA1c were hemolyzed and then proportionally mixed. Linear regression analysis of the 2.2-min protocol data gave a relationship of $y = 1.0x - 0.62; r = 0.995$; analysis of the 3.0-min protocol gave a relationship of $y = 0.986x + 0.15; r = 0.999$.

**Method Comparisons**

Comparisons for the 2.2-min protocol were made against the local established method, a Bio-Rad Diamat (Paris laboratory), using bloods from 319 diabetic and nondiabetic subjects being routinely monitored. Initial evaluation of the intermethod bias revealed three extreme outliers (Fig. 2). Further examination of the data showed that two of these samples had the highest L-A1c fractions among these subjects, at 5.7% and 6.1%. These outliers were omitted from Passing and Bablok regression analysis, which gave a slope (95% confidence interval) of 0.97 (0.95–0.98) and an intercept of 0.16 (0.04–0.25).

Samples from 137 diabetic and nondiabetic subjects were analyzed using the 3.0-min protocol, and the results were compared with the local established method, a Bio-Rad Variant (Newcastle laboratory). Initial evaluation of intermethod bias revealed four extreme outliers in the

<table>
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<th>Within-run Imprecision</th>
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* QC, quality control.
group (Fig. 3). Further examination of the data showed that all of these samples had urea concentrations above the age-related reference interval. These outliers were omitted from Passing and Bablok regression analysis which gave a slope (95% confidence interval) of 1.00 (0.98 – 1.00) and intercept of 0.80 (0.80 to 0.63).

REFERENCE INTERVAL
Reference values for healthy nondiabetic volunteers were 4.3–5.4%, with a mean of 4.9%. These were obtained by use of Tosoh calibrators with values assigned by the Japanese Diabetic Society. DCCT-aligned values for the calibrators are now also available, and these are ~0.5% higher.

LABILE FRACTION
For bloods incubated with glucose concentrations up to 50 mmol/L and for up to 6 h, the chromatographically identified S-A1c peak did not show a change beyond method reproducibility. Peaks identified as L-A1c showed increases as a function of both time and glucose concentration, which after a 6-h incubation were 39–233% higher than the values of nonincubated samples.

When subjected to chemical modification by progressively longer incubation in borate-buffered solution, the L-A1c peak values were similar between primary and preincubation samples but diminished post incubation. However, in all cases a substantial remnant varying from 58% to 85% of the original peak value persisted, suggesting that the fraction is of a heterogeneous nature.

During storage over a 21-day period of undiluted blood samples with initial S-A1c percentages of 6.9–10.7%, the labile fraction diminished by 32–63% of the original value. In the same samples, the absolute change in the stable fraction was no greater than 0.2%, which is within 2.8 SD of the initial values and, therefore, not significant.

CARRYOVER
Carryover was 1.2% in the 2.2-min protocol and 0.3% in the 3.0-min protocol. Both are within the achievable reproducibility of the system under these conditions.

SAMPLE SEDIMENTATION
The largest absolute changes in measured HbA1c values for samples with concentrations up to 10.2% and that were subjected to a maximum 5-h sampling delay period were 0.1% HbA1c (relative percentage changes of 1.9% at 5.4% HbA1c, 1.0% at 10.2% HbA1c, and 0% at 7.1% HbA1c). These differences fall within method reproducibility for the 3.0-min protocol.

HEMOGLOBIN LOAD
Sample dilution ratios of 1:1000 to 1:50 gave total chromatographic areas of 363-5284 units in the 2.2-min protocol. Areas between 700 and 4000 provided good resolution and satisfactory integration as judged subjectively. The same range of dilutions with the 3.0-min protocol gave total chromatographic areas ranging from 338 to 8080 units. Qualitative assessment of these chromatograms indicated that the acceptable area range was 500-6000 units.

HEMOLYSATE STABILITY
All results obtained on hemolysates analyzed repeatedly over a 7-h period agreed to within 0.1% HbA1c compared with the parent blood samples analyzed at the same time. Longer storage at room temperature was unsatisfactory.
Fig. 4. Tosoh chromatograms for a variety of hemoglobins (labeled peaks), showing the resolution of the 3.0-min protocol. 
(A and B), HbC in the 2.2- and 3.0-min protocols, respectively. (C), unresolved HbE in the 2.2-min protocol, which becomes apparent in the 3.0-min version (D). (E–H), 3.0-min protocol chromatograms for HbD (E), HbS (F), HbTyne (G), and HbF (H). The shaded peak is HbA1c.
Stability of hemolysates was acceptable for up to 24 h if stored at 4 °C.

INTERFERENCES
No interference was observed with up to 10 mmol/L triglyceride and 400 μmol/L bilirubin on a sample with 5% HbA1c.

CARBAMYLLATION
On the Tosoh the S-A1c peak was unaffected; only the labile fraction increased and this was by 20% L-A1c at the maximum cyanate concentration. However, the peak measured as HbA1c on the Diamat increased artifically to an apparent 28.7% HbA1c at the same cyanate concentration. In these prolonged incubation experiments, hemoglobin degradation was indicated in the Diamat chromatograms by a marked baseline rise, which may be the cause of some of the increases seen in Diamat results.

HEMOGLOBINOPATHIES
The relative utility of the two protocols in demonstrating the presence of hemoglobin variants was investigated using samples containing HbAC, HbAE, HbAD, HbF, HbAS, and HbTyne (7) and showed superior identification for the 3.0-min version (Fig. 4).

Discussion
A high level of reproducibility in glycohemoglobin measurement is a fundamentally important requirement in the provision of laboratory support for the process of diabetes monitoring. Changes in results obtained between patient visits to the physician must reflect the pathology of the disease and its response to treatment rather than analytical uncertainty. In this respect, biological variation generally has dictated the desirable targets for analytical performance of laboratory methods (8). However, it has been shown that the situation in persons with diabetes is more complex, being affected by both clinical control and sampling time interval (9), and a practical working CV for analytical reproducibility in long-term monitoring of 2.1% has been proposed (10). The Tosoh analyzer achieved this stringent target in our evaluations and has maintained this performance in extended routine use in both laboratories using the 3.0-min protocol.

Although reproducibly measured glycohemoglobin is an essential prerequisite for diabetes monitoring, its clinical value is greatly enhanced by relating these measures to likely clinical outcome. This is best achieved by reference to the now well-established evidence base found in DCCT for type I diabetes (1) and to the more recent corroborative data from the UK Prospective Diabetes Study for type II (2). The American Diabetes Association recommends that diabetes monitoring using glycohemoglobin should be performed only with DCCT-traceable methods (11). Differences in bias observed in the relationship of the Tosoh instruments to the two different Bio-Rad systems were calibration dependent and serve to empha-
using either protocol, is its ability to chromatographically resolve the labile fraction, thus obviating the need for pre- or on-column treatment to destroy this fraction before analysis. We have confirmed that the labile fraction is separated on the Tosoh system, irrespective of its concentration. The benefit of this is demonstrated in the comparison with the locally used routine methods. For example, with the Bio-Rad Variant, we had to use an extended preanalysis incubation to minimize this confounding factor. Others have also reported that standard Bio-Rad Variant procedures may be inadequate for some samples encountered in routine laboratory practice (15). Similar limitations may affect analyzers utilizing on-column labile fraction degradation but which lack labile/stable fraction chromatographic resolution.

The presence of uremia in patients whose long-term glycemic status is being assessed is not an uncommon finding in those whose renal function has deteriorated, and it can provide yet another potential interference with some, although not all, glycohemoglobin methods (16). Although the evidence from our labile fraction experiments suggests that the L-A1c peak does contain all of the labile entity, it also shows that it is not the sole component. We demonstrated that this peak includes, among other things, carbamylated hemoglobin. This raises the question of how other chromatographic systems with lower resolution capabilities handle these unidentified and potentially interfering components or whether they remain as occult effects (17). In our Bio-Rad Variant/Tosoh comparison, the extreme outliers with increased urea concentrations demonstrated the problem of coelution of carbamylated hemoglobin with HbA1c on the Variant. In the Bio-Rad Diamat/Tosoh study, we also demonstrated an artifactual effect of adduct formation on measured HbA1c, which was eliminated on the Tosoh analyzer by virtue of its superior chromatographic resolution.

An additional benefit of enhanced resolution is the ability to detect the presence of hemoglobinopathies, and in this respect the 3.0-min protocol was superior to the 2.2-min protocol for the hemoglobin variants we investigated. Abnormal concentrations of normal hemoglobins such as HbF are also clearly recognized on the Tosoh, which is important in persons with diabetes in whom there is an increased prevalence (18). In the 3.0-min mode, it is less likely that any hemoglobin structural abnormality will go unrecognized and that the apparent HbA1c will be inappropriately reported. The similarity between the chromatograms for the relatively common HbE and the very rare HbTyne show that the analyzer cannot be used with either of the protocols we evaluated to classify hemoglobinopathies but only to indicate their presence. Mathematical elimination of unusual peaks in the calculation of results does not guarantee that the calculated result is a valid or appropriate measure of HbA1c. What is important is that the presence of any abnormality is readily detected by the busy analyst for further consideration of its implications by the physician.

This joint evaluation has shown that the Tosoh A1c 2.2 performs to high analytical standards and has several advantages over other HbA1c HPLC systems available at this time, not the least of which is its high chromatographic resolution. Certain of its features, particularly its speed, lack of requirement for frequent calibration, low maintenance, and safe primary sampling capability, make it equally as well suited for diabetes clinic/near-patient testing applications as for intensive central laboratory use.

We thank Eurogenetics, Belgium, for providing the analyzers and reagents used in these evaluations.

References


