RESEARCH LETTER

Comparison of Point of Care and Laboratory HbA1c Analysis: A MetroNet Study

Kendra L. Schwartz, MD, MSPH, Joseph Monsur, BS, Adnan Hammad, PhD, Monina G. Bartoces, PhD, and Anne Victoria Neale, PhD, MPH

Background: Evaluating new technology in clinical practice is an important component of translating research into practice. We considered the feasibility of using a Clinical Laboratory Improvement Amendments (CLIA)-waived point of care (POC) glycohemoglobin (HbA1c) methodology in busy family medicine centers by comparing the results of POC HbA1c and laboratory analysis results.

Methods: Recruited from 5 MetroNet practices, the participants were adult diabetic patients having blood samples drawn for laboratory analysis of HbA1c. Each agreed to provide a capillary blood sample for POC testing.

Results: With data on 99 paired samples, the POC method yielded a mean HbA1c of 7.38%, which was equivalent to the mean of 7.53% produced with all combined standard laboratory analyses. The Pearson correlation between POC and the laboratory analysis test results was 0.884 ($P < .001$). POC test sensitivity was 81.8% and specificity was 93.2%. Eighteen percent of patients with an HbA1c $\geq$7% by laboratory analysis were not identified as such by the POC test.

Conclusions: Before adopting a POC methodology, practices are encouraged to review its feasibility in the context of the office routine, and also to conduct periodic comparisons of the accuracy of POC test results compared with those from laboratory analysis. (J Am Board Fam Med 2009;22:461–3.)

Point of care (POC) glycohemoglobin (HbA1c) testing offers potential benefits for diabetes care, especially for patients who experience barriers to traveling to laboratories for blood draws or to repeated follow-up visits.[1] Research has demonstrated that the availability of HbA1c test results provided during the same visit is associated with improvement in glycemic control.[1,2]

Studies comparing HbA1c POC test results with those from laboratory analyses suggest the need to evaluate a given POC methodology before concluding that the 2 methods of testing are inter-changeable. Reported concerns include a wide range in individual POC HbA1c values[3,4]; indications that the most accurate POC HbA1c values were within a range of 6% to 8%[5]; and between-batch imprecision estimates exceeding 5%.[6]

Other research has compared POC testing in a single practice or a controlled research setting; however, our objective was to compare the results from a POC HbA1c test with laboratory HbA1c measurements taken in busy clinical practice settings. Evaluating new technology in clinical practice with non–laboratory-trained personnel is an important component of translating research into practice. In a previous study we explored the feasibility and utility of introducing a multistep POC device into clinical practice.[4] Medical assistants found it difficult to integrate the particular device into their routines because it required several timed steps. Soon after that study, new 1-step POC devices that took less staff time and had less potential for making errors became available. We repeated our first study to determine whether a 1-step POC device (with fewer opportunities for error) would perform better and be more accepted by staff. Rather than critique a particular medical technol-

ogy, per se, our objective was to consider the factors that would affect a decision to adopt a new approach to HbA1c testing. The focus of this article is to demonstrate the usefulness of conducting a similar mini-study when deciding to adopt a POC device in primary care practice.

Methods

Study Design

In this cross-sectional study, diabetic patients were recruited from 5 family medicine centers (FMCs) that were members of MetroNet, a metropolitan Detroit primary care practice-based research network. At all sites HbA1c analysis was routinely performed at an outside laboratory using venipuncture samples. Eligibility criteria were diabetic patients 18 years of age or older whose physicians ordered HbA1c analysis for routine care. Physicians and medical assistants identified consecutive eligible patients, explained the study, and obtained informed consent from those who wished to participate. To standardize procedures, a finger-prick blood sample was collected for in-office HbA1c testing with Metrika A1c Now (Bayer Health Care, Sunnyvale, CA), a rapid one-step test. A venous sample was also collected and analyzed at an off-site laboratory as usual. Physicians were blinded to POC HbA1c results and relied on laboratory HbA1c results for clinical decision making.

The 5 FMCs used 4 different laboratories for venous sample analysis, all of which were aligned to Diabetes Control and Complications Trial[7] and National Glycohemoglobin Standardization Program standards. The Clinical Laboratory Improvement Amendments-waived POC device used was National Glycohemoglobin Standardization Program certified and aligned to the Diabetes Control and Complications Trial trial. It provided results in approximately 9 minutes within a self-contained, single-use monitor.

Analytic Strategy

Pearson correlations were calculated to compare the performance of the POC method to standard laboratory analysis. To test the null hypothesis of nonequivalence (a difference of ±1% in HbA1c) between the methods, we used the paired equivalence t test to determine whether the HbA1c value from the POC test was equivalent to the value from the laboratory test.

Table 1. Sensitivity and Specificity of a Point of Care (POC) Glycohemoglobin (HbA1c) Test at 7% Cut Point Compared to Laboratory Test Results*

POC test (%)	Laboratory	
	HbA1c ≥7 (%)	HbA1c <7 (%)
HbA1c ≥7	45	3
HbA1c <7	10	41
Total	55	44

*Sensitivity (45 of 55), 81.8%; specificity (41 of 44), 93.2%; positive predictive value (45 of 48), 93.8%; false negative (10 of 55), 18.2%; false positive (3 of 44), 6.8%.

Results

Complete data for 99 paired samples were available for analysis. The average number of patients entered into the study from each of 5 FMCs was 20 (range, 11–27). The 99 laboratory samples had a mean HbA1c of 7.53%, equivalent to the mean of 7.38% produced with the POC methodology ($P <$ .0001 to reject the null hypothesis of nonequivalence). The range of Pearson correlations from the 4 laboratory methodologies was 0.74 to 0.96. For all samples combined, we found a significant correlation between laboratory and same-visit test results (Pearson r = 0.884; $P <$ .001).

Sensitivity and Specificity

Current practice guidelines recommend intensifying therapy in patients with HbA1c levels greater than 7.0%.[8] To evaluate the clinical usefulness for therapy adjustments of the POC technology, we compared its results to the laboratory results at a treatment threshold of 7.0% HbA1c. The sensitivity of the POC method was 81.8% and specificity was 93.2% (Table 1). Therefore, in this study, approximately 18% of people with an HbA1c more than 7% by laboratory analysis were not identified as such by the POC test.

Discussion

POC HbA1c testing may provide adequate accuracy and be useful for some patients, especially those who cannot obtain laboratory results secondary to either financial or transportation constraints, but the decision to make adjustments in therapy should be made cautiously when first switching over from laboratory testing.[5] Extrapolating our data to a hypothetical scenario, 82% of patients with HbA1c ≥7% would have their treatment in-

tensified using the POC test method compared with laboratory testing. The 18% false-negative HbA1c finding is concerning.

The correlation between laboratory and POC methodologies would probably be improved under more controlled conditions where sources of variation are minimized, such as those in the operation of the POC HbA1c device, as well as the variation between laboratory methodologies. Although the number of medical staff who collected samples and performed the HbA1c testing may have increased the variability of the same-visit results,[9] in the context of translating research into practice we suggest that this is a study strength rather than limitation.

Physicians and staff were quite positive about the POC device used in this multisite study; they agreed that it was feasible and acceptable to use and compared favorably with their routine of usual care. However, before clinicians incorporate POC methodologies into their office routine, we suggest they conduct a similar comparison of the particular POC method with their current practice to evaluate feasibility, acceptability, and accuracy; this should be repeated periodically.[10] Additional research is needed to determine how POC testing might improve care for vulnerable and underserved populations.[9]

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