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Point-of-Care HbA1c Testing with the A1cNow Test Kit in General Practice Dental Clinics: A Pilot Study Involving Its Accuracy and Practical Issues in Its Use

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Abstract

With millions of at-risk people undiagnosed with pre-diabetes and diabetes, there is a need to identify alternate screening sites for out-of-range glucose values. We examined practical issues and accuracy (relative to High Performance Liquid Chromatography testing in a laboratory) in the use of the A1cNow point of care device for this screening in general practice dental clinics at a large University-based Dental College. Health care professionals obtained evaluable readings for only 70% of the subjects, even after two attempts, and its use according to manufacturer's

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instructions was often challenging in the busy environment of the dental clinic. At thresholds for pre-diabetes and diabetes established by the American Diabetes Association, sensitivities of the A1cNow kit relative to the HPLC method were 91.9% and 100%, respectively. However, specificities for pre-diabetes and diabetes were 66.7% and 82.4%, respectively, indicating many false positive results. A better strategy for diabetes screening may involve a laboratory-based analysis approach that is patient- and provider-friendly, with minimal burden to the dental team.

Keywords

A1c; diabetes screening; dental visit; point of care

INTRODUCTION

In 2010, 18.8 million people in the United States had been diagnosed with diabetes, a condition that is associated with many medical complications, among them neuropathy, retinopathy, and periodontitis.¹ In fact, diabetes is a leading cause of renal failure, cardiovascular disease, blindness, and non-traumatic lower limb amputations, and rates of diabetes-related mortality are especially high.¹ Of special concern is that 7 million people living with diabetes in the United States were undiagnosed in 2010,¹ with the number of undiagnosed people expected to continue to rise.² Because of the mild or asymptomatic nature of diabetes in its early stages, many individuals have diabetes for several years before being diagnosed.³ By the time of diagnosis, the functioning of beta cells in storing and releasing insulin may have declined substantially,⁴ and significant damage may already have occurred. Notably, diabetes screening can enable earlier detection, leading to earlier lifestyle changes and/or medication treatment. This may help prevent, delay, and manage the long-term complications of diabetes that reduce quality of life and increase morbidity and mortality.⁵⁻¹⁵

To facilitate earlier identification of diabetes, some have advocated for opportunistic screening among at-risk persons who present for health care unrelated to diabetes.^{5,16-20} For example, as emergency department (ED) patients have a high prevalence of unrecognized diabetes,²¹ especially among minority and vulnerable populations for whom the ED is often used as a safety-net source of medical care,²² the ED may be an important alternate venue for diabetes screening. Other nontraditional sites where persons at risk for diabetes can be screened include optometry offices and pharmacies.^{23,24} In addition, the high risk for diabetes among individuals with periodontal disease²⁵⁻³⁰ has motivated some to suggest the potential of the dental visit as another opportunity for diabetes screening.³¹⁻³⁴

Screening for diabetes, in whatever the venue, can be performed in a variety of ways, among them surveys that evaluate diabetes risk and blood tests for glucose levels.^{5,35-37} With regard to blood tests, measurement of hemoglobin A1c (HbA1c) has distinct advantages over other glucose tests (i.e., oral glucose tolerance and fasting plasma glucose). HbA1c provides a summary measure of glycemic control over a 3-month period, can be obtained at any time of day, does not require fasting or other patient preparation, is relatively stable at room temperature, and is considered to be unaffected by transient hyperglycemia from acute

stress or illness.³⁸ Although frequently measured in the laboratory, HbA1c can also be measured using point-of-care technology, such as the Bayer A1cNow test kit. Typically used for the determination and monitoring of diabetic patients' glycemic control,³⁸⁻⁴² the A1cNow test kit's small, portable, disposable handheld immunoassay device is certified by the National Glycohemoglobin Standardization Program, and is Clinical Laboratory Improvement Amendments (CLIA) waived. Requiring no calibration, it uses a small (5µl) blood sample that is mixed with a reagent provided with the test kit, and then transferred with a pipette to a sample well in the testing device.⁴³ Results are provided in 5 minutes. Although some studies have demonstrated that the A1cNow assay results are not comparable to those obtained in the laboratory,⁴⁴⁻⁴⁷ other studies have found a high level of such comparability.^{43,48} In addition, the ease of use of the A1cNow test kit has been examined among both healthcare professionals and lay users in achieving accurate HbA1c measurements.⁴⁹ Although the A1cNow test kit was recently used as a diabetes screening test in a multisite study at dental visits,⁵⁰ to our knowledge, its ease of use and accuracy relative to a reference laboratory among patients with and without diabetes has not specifically been examined when used at general practice dental clinics.

As one component of a National Institute of Dental and Craniofacial Research (NIDCR)-funded study that is examining the acceptability and feasibility of measuring HbA1c to screen for diabetes using finger stick or oral blood at dental visits, we examined the accuracy and practical issues in the use of the A1cNow device in general practice dental clinics at a large University-based Dental College. To do so, over a 3-month period, we collected two finger stick samples from dental patients participating in the study: one sample for analysis of HbA1c in a laboratory and the other for analysis using the A1cNow test kit. After reporting on practical aspects of its use in the dental venue, we examine the accuracy of the A1cNow test kit relative to laboratory testing.

MATERIALS AND METHODS

Patient Recruitment, Eligibility, and Survey Completion

The study was designed as a prospective evaluation and was approved by the New York University (NYU) Medical Center Institutional Review Board. Members of our research team recruited patients waiting for their dental appointments in the 14 general practice clinics at the NYU College of Dentistry. These clinics serve a patient pool of approximately 100,000 male and female patients annually, of diverse ages and races/ethnicities. Many are of low socio-economic status, including about 1/3 covered by Medicaid, with the clinics serving as a "safety net" oral health provider for these patients.

After describing the research study and answering potential participants' questions, research team members obtained informed consent from persons interested in taking part in the study. Patients then completed an eligibility questionnaire, with study eligibility requiring that they: (1) be at least 18 years of age, (2) have diabetes or be at risk for it according to American Diabetes Association criteria,⁵ (3) self report that they have gums that bleed, and (4) do not require antibiotic premedication before dental treatment, nor have a history of severe cardiovascular, hepatic, immunological, renal, hematological, or other organ impairment. (We included patients with previously diagnosed diabetes in order to obtain a

full range of HbA1c values.) Patients who were found not to be eligible for the research were thanked for their interest and given a \$5 gift card. Eligible patients were asked to complete a pre-dental visit questionnaire in the reception area of the general practice clinics. In addition to their socio-demographic characteristics and systemic and oral health-related activities, the questionnaire asked about participants' diabetes knowledge and its relationship to periodontal disease, sources of this knowledge, the psychological impact of diabetes screening, feelings and worry about diabetes, and thoughts about screening for it in the dental venue. At the conclusion of the dental visit, during which blood samples were collected for measuring HbA1c (as described below), a research team member oversaw the patient's completion of a brief post-dental visit survey, assessing the patients' experience with the diabetes screening. Participants were provided with a \$25 gift card.

Finger Stick Blood Collection and HbA1c Testing

From June through early September, 2013, finger stick blood (FSB) was collected by trained registered nurses (RNs) and baccalaureate nursing students for two approaches to HbA1c testing from 87 eligible patients while they were seated in the dental chair. Blood collection was supervised by a PhD-prepared, nationally certified nurse practitioner who was also a faculty member at the NYU College of Nursing and a co-investigator on the study.

High Performance Liquid Chromatography (HPLC) Testing of HbA1c—HbA1c was measured in a FSB sample using a HPLC assay. A micropipette was used to draw 10 microliters of blood. It was evenly distributed onto pre-drawn circles on Whatman 903 filter paper and allowed to dry for one hour at room temperature. The filter paper was then placed in a plastic bag and stored at 4°C, and transported within 7 days at 4°C to the Center for Advanced Laboratory Medicine at Columbia University Medical Center (CUMC). Each specimen was labeled with a unique identification code for the patient from whom it was collected.

HbA1c was measured using the D-10 HPLC analyzer from BIO-RAD Laboratories.⁵¹ The HPLC method is automated and uses ion-exchange chromatography to separate the hemoglobin fractions. Blood was injected onto a column containing a negatively charged cation exchange resin that has an affinity for the positively charged hemoglobins. Buffers of increasing ionic strength pass through the column and the hemoglobin fractions are separated based on their ionic interactions with the column. The separated hemoglobin fractions then pass through the flow cell of the filter photometer where the absorbances are measured at a wavelength of 415nm. An additional filter at 690nm corrects for background absorbance. A sample report, including the retention times of the detected peaks and a chromatogram, is generated for each sample by the software program. The HbA1c level is obtained using an exponentially modified Gaussian algorithm. The D-10 HPLC method is traceable to the reference methods of both the National Glycohemoglobin Standardization Program and the International Federation of Clinical Chemistry and Laboratory Medicine.⁵¹

The Center for Advanced Laboratory Medicine laboratory at CUMC entered the HbA1c results for each de-identified patient sample into a database and sent it securely to the study's Principal Investigator. The HPLC results were considered the true reference results.

A1cNow Testing of HbA1c—After training in its use according to manufacturer guidelines, RNs and nursing students also collected FSB that was tested for HbA1c using the Bayer A1cNow test kit. The kits were checked to assure that expiration dates had not passed, were kept refrigerated, and were allowed to come to room temperature before they were used.

The A1cNow monitor is a disposable, 4-channel reflectance photometer immunoassay device integrated with dry reagent chemistry strips and contained within a sealed plastic case.

Each A1cNow test kit consists of a monitor; a sample dilution kit (a vial of sample dilution buffer, a capillary pipette, a transfer pipette, and a tube holder); a lancet; and a package insert. To measure HbA1c with the A1cNow test kit, the finger was cleansed with alcohol, allowed to dry, and then lanced to obtain a drop of blood. A 5µl capillary blood sample was collected and added to the sample dilution buffer. The diluted sample was mixed and added to the monitor using the transfer pipette. Once the sample was applied, the monitor began the analyses. Digital results were displayed in the display window after 5 minutes. The test result was recorded for each patient. In the event of a procedural error or a monitor error, an error code appeared in the monitor's window. If this occurred, a second test was performed for the patient, and the test result was recorded. In the event that the second test also produced an error code, the failure of this second test attempt was recorded for the patient. The laboratory was blinded to the A1cNow test kit results.

Statistical Analysis

In the context of the practical use of the A1cNow test kit, we first determine the proportion of participants for whom we were able to obtain a HbA1c reading and the special challenges in using the A1cNow test kits in the dental venue. After describing the socio-demographic characteristics of participants from whom we were able to obtain such a reading, we use various approaches to examine the accuracy of the A1cNow test kits relative to the reference laboratory. We first compute Pearson's correlation coefficient between hemoglobin A1c as determined by the point-of-care A1cNow test and the reference laboratory method (HPLC). Pearson's correlation coefficients are also computed separately for values above and below 5.7% and 6.5%, the thresholds for pre-diabetes and diabetes, respectively, as established by the American Diabetes Association.⁵ We then examine if there is a statistically significant difference between HbA1c as measured by the A1cNow test kit and the reference laboratory. We follow with a determination of the proportion of HbA1c values as measured by the A1cNow test kit that are above and below the laboratory reference. Finally, we examine the sensitivity and specificity of the HbA1c measures using the A1cNow test kit relative to the laboratory measures at each of the 5.7% and 6.5% thresholds.

RESULTS

Practical Issues in the Use of the A1cNow Test Kits

Of the 87 eligible participants in the research study from June through early September, 2013, there were 61 participants (70%) for whom we were able to obtain HbA1c measures

using the A1cNow test kits. Although we attempted to obtain HbA1c readings using the A1cNow test kits twice from the remaining 26 participants, error messages appeared each time. A total of 8 trained RNs and nursing students collected the blood samples for the A1cNow and laboratory HbA1c analyses: two nurses together collected samples from 67 participants, with 46 (69%) evaluable with the A1cNow kit; and 6 nursing students together collected samples from 20 participants, with 15 (75%) evaluable. As evidenced by the high rate of failure to obtain a HbA1c reading from the A1cNow test kit, the trained RNs and nursing students who collected the blood samples found this point-of-care device difficult to use in the dental venue. In the crowded workspace of the dental clinic, it was hard to follow manufacturer's instructions in finding a suitable surface on which the monitor could remain flat and untouched for five minutes while the blood sample was being analyzed. It was also unclear at what intensity to shake the dilution vial to ensure proper mixing of the dilution buffer and the participant's blood sample. Shaking the dilution vial at an intensity that was either too vigorous or too slow would sometimes yield an error message. Lastly, placing the dilution vial into the cartridge and initiating the sample release into the monitor sometimes resulted in a procedural error message. Repeatedly, not enough of the sample was released to be analyzed and would spill onto the workspace, resulting in a failed attempt to obtain an HbA1c reading.

Participant Socio-demographics and Diabetes Risk

Of the 61 participants whose HbA1c was measured with both the A1cNow test kit and in the laboratory, 60.7% was female. While all were at least 18 years of age, 65.6% were between the ages of 45 and 65, and 14.8% were older than 65. Regarding their race/ethnicity, 42.6% were White, and almost all of the other participants were Latino (34.4%) or Black, African American, or Caribbean (21.3%). In all, 60.7% had at least some college education, and 23.7% were educated through high school. A little over a quarter of the participants (26.2%) had been told by a primary care provider that they had diabetes. Among those who had never been told by a clinician that they had elevated blood glucose, 68.9% had a body mass index (BMI) ≥ 25 kg/m², 51.1% got little or no exercise on a given day, and one third (33.3%) had a parent or sibling with diabetes.

Accuracy of the A1cNow Test Kit

HbA1c values for the 61 participants using the A1cNow device ranged from 4.0 to 11.0, with a mean of 6.3, a standard deviation of 1.4, a median of 6.0, and an interquartile range (IQR) of 5.4 to 6.6. HPLC measurement of HbA1c ranged from 4.6 to 10.1 with a mean of 6.1, a standard deviation of 1.1, a median of 5.8, and an IQR of 5.5 to 6.3. The Pearson correlation between the two HbA1c measures was 0.917 ($p < .005$). While the correlations remained significant for values below and above HPLC measurements of 5.7% ($p < 0.01$), there was a stronger correlation between tests for values $\geq 5.7\%$ ($r = 0.904$) compared with those below 5.7% ($r = 0.617$). Data were further dichotomized using the hemoglobin A1c value cutoff of 6.5%, as determined by the HPLC measurement. The correlation coefficients were $r = 0.718$ and 0.929 for values less than and greater than 6.5%, respectively, and were statistically significant ($p < .005$).

The distributions of the HbA1c values for the A1cNow and HPLC analyses were not normal (skewness of the A1cNow results and HPLC analyses were 1.6 and 2.0, respectively; kurtosis was 3.0 and 4.3, respectively). We therefore used a non-parametric test (related samples – Wilcoxin signed rank test) to determine whether there were statistically significant differences in the paired HbA1c values as measured by the two ways of measuring HbA1c. Results indicate that the median of differences between the two HbA1c measures was not 0, demonstrating that the two HbA1c measures were significantly different ($p=.004$). This can be seen graphically in Figure 1: 63.9% of the HbA1c values assessed using the A1cNow test kit were greater than the HPLC values (i.e., appear in the Figure above the diagonal line on which equal HbA1c values on the two assessment methods would appear), 29.5% were less than the HPLC values (i.e., below the diagonal line), and 6.6% were the same as the HPLC values.

Sensitivity and Specificity of the A1cNow test kit

To evaluate the clinical usefulness for identifying persons with out-of-range glucose values (i.e., in the pre-diabetes or diabetes ranges), and those that are in the diabetes range, we compared A1cNow results to the HPLC results at thresholds of 5.7% and 6.5%, respectively. At a threshold of 5.7%, the sensitivity of the A1cNow method was 91.9% and specificity was 66.7%. Therefore, approximately 8% of participants with an HbA1c of at least 5.7% by HPLC analysis were not identified as such by the A1cNow test, and one third of participants (33.3%) with an HbA1c value less than 5.7% according to the HPLC results were incorrectly identified as having out-of-normal-range results using the A1cNow analysis. At a threshold of 6.5%, the sensitivity of the A1cNow method was 100% and specificity was 82.4%. Thus, while no individual who had a HPLC value in the diabetes range failed to also have a value in the diabetes range using the A1cNow device, almost 18% of persons with an HbA1c value less than 6.5% according to the HPLC results were incorrectly identified as having values in the diabetes range using the A1cNow analysis.

DISCUSSION

Facilitated by the 2010 ADA promotion of the HbA1c test for diabetes diagnosis⁵² and the advent of HbA1c portable testing devices such as the A1cNow testing kit, the potential to screen at-risk patients for diabetes at dental visits has increased. Our results demonstrate that the correlation of HbA1c results from blood collected from dental patients and analyzed by HPLC and using the A1cNow device are high (0.917). This was especially the case for HbA1c HPLC results greater than the pre-diabetes threshold of 5.7% and the diabetes threshold of 6.5% (0.904 and 0.929, respectively). However, our analyses indicate that the HbA1c readings from the A1cNow test kit and the HPLC assay are statistically significantly different ($p=.004$), and that in almost two thirds of the cases, HbA1c values assessed using the A1cNow test kit were greater than the HPLC values. Of considerable concern is the proportion of false positives for out-of-range HbA1c values using the A1cNow test kit relative to the HPLC readings: 33.3% at a threshold of an HbA1c of 5.7%, and 17.6% at threshold of an HbA1c of 6.5%. These false positive readings may result in worry, anxiety, and reduced perceived health, and predispose patients to higher levels of perceived threat concerning diabetes screening.⁵³⁻⁵⁵

Regarding the practical use of the A1cNow device, a study by Chang and colleagues⁴⁹ evaluated its performance to measure HbA1c when used by 110 lay users with and without diabetes (with 80% under 55 years of age) and 109 health care professionals. In this study, lay subjects performed two A1cNow self-tests, followed by a test of the subject's HbA1c by a health care professional.⁴⁹ A total of 177 of the 215 tests performed by the lay users (82%) yielded numerical results, with 74 of the 110 lay users (67%) obtaining a numeric value on both of their A1cNow tests. In addition, 99 of the 109 health care professional tests (91%) resulted in evaluable readings. In our study, health care professionals (i.e., trained RNs and nursing students) obtained evaluable readings using the A1cNow tests for only 70% of the subjects, even after two attempts. Notably, while the A1cNow test kit has been used at dental visits both for examining the relationship between periodontitis and HbA1c values for persons with undiagnosed diabetes as well as for diabetes screening,^{50,56,57} our study is the first to report the proportion of failed attempts in this venue to obtain a reading from the A1cNow device. Based on RN and nursing students' experience in a dental clinic, obtaining an HbA1c reading from the A1cNow kit can be complicated, especially in finding a flat surface on which to place the monitor and leave it undisturbed for sample analysis, determining the correct intensity to shake the dilution vial, and inserting the vial into the cartridge and initiating the sample release.

While some challenges in using the A1cNow test kit at a dental clinic are unique to this venue, others apply whatever the context of use. In fact, in the study by Chang and colleagues,⁴⁹ the vast majority (94%) of lay subjects rated the overall A1cNow testing experience as "very good" or "excellent." However, a much smaller proportion felt as positively about the testing time and the ease of inserting the blood collector into the shaker. For patients with diabetes who wish to monitor their condition using the A1cNow test kit, managing the kit's components may present challenges, especially for those who already suffer from complications of the disease, such as decreased sensation and decreased vision acuity.⁵⁸ This may especially be the case for older patients with diabetes, as the kit contains small components that require dexterity that may be compromised from age-related changes.⁵⁹

We acknowledge the relatively small sample size as a limitation to the research. Nonetheless, with an increasing dialogue concerning the potential of the dental visit to serve as a site of opportunity for diabetes screening among at-risk populations, this study provides preliminary data to illuminate some of the challenges that may be encountered when using a point-of-care HbA1c device in the dental venue. It suggests that a better strategy for diabetes screening may involve a laboratory-based analysis approach that is patient- and provider-friendly, with minimal burden to the dental team.

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Figure 1.

HbA1c as measured by the HPLC Assay and the A1cNow test kits (N=61)

HbA1c. Hemoglobin A1c

HPLC. High Performance Liquid Chromatography