Can J Diabetes 40 (2016) 242–246

Contents lists available at ScienceDirect

Canadian Journal of Diabetes

journal homepage: www.canadianjournalofdiabetes.com

Original Research

Agreement of Point-of-Care Capillary Glycated Hemoglobin Levels with Conventional Screening Tests for Diabetes Mellitus in a Canadian First Nations Population

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ARTICLE INFO

Article history:
Received 8 August 2015
Received in revised form
3 November 2015
Accepted 9 November 2015

Keywords:
glycated hemoglobin
glycohemoglobin
Aboriginal
Indians, North American (MeSH)
Indigenous population (MeSH)
type 2 diabetes

ABSTRACT

Objectives: 1) How closely do capillary glycated hemoglobin (A1C) levels agree with venous A1C levels? 2) How well do venous A1C levels agree with plasma glucose for diagnosis of diabetes in this population? *Methods:* The Seabird Island mobile diabetes clinic screened people not known to have diabetes by using finger-prick capillary A1C levels with point-of-care analysis according to the Siemens/Bayer DCA 2000 system. Clients then went to a clinical laboratory for confirmatory testing for venous A1C levels, fasting plasma glucose (FPG) and plasma glucose 2 hours after 75 g oral glucose load (2hPG). A reference laboratory compared the DCA 2000 and the clinical laboratory's Roche Integra 800CTS system to the National Glycohemoglobin Standardization Program Diabetes Control and Complications Trial (DCCT) reference. *Results:* 1) In the reference laboratory, DCA 2000 and Integra 800CTS both agreed very closely with the DCCT standard. In the field, capillary glycated hemoglobin percent (A1C) % was biased, underestimating venous A1C % by a mean of 0.19 ($p<0.001$). The margin of error of bias-adjusted capillary A1C % was ±0.36 for 95% of the time, compared to ±0.27 for venous A1C%. 2) By linear regression, we found FPG 7.0 mmol/L and 2hPG 11.1 mmol/L predicted mean venous A1C levels very close to 6.5%, with no significant bias. *Conclusions:* Point-of-care capillary A1C did not perform as well in the field as in the laboratory, but the bias is correctible, and the margin of error is small enough that the test is clinically useful. In this population, venous A1C levels ≥6.5% agree closely with the FPG and 2hPG thresholds to diagnose diabetes; ethnic-specific adjustment of the venous A1C threshold is not necessary.

Mots clés :
hémoglobine glyquée
glycohémoglobine
Autochtone
Indiens d'Amérique du Nord (Inserm)
population indigène (Inserm)
diabète de type 2

RÉSUMÉ

Objectifs : 1) Dans quelle mesure les taux d'hémoglobine glyquée (A1c) du sang capillaire correspondent-ils aux taux d'A1c du sang veineux? 2) Dans quelle mesure les taux d'A1c du sang veineux correspondent-ils à la glycémie veineuse pour le diagnostic du diabète de cette population? *Méthodes :* La clinique mobile de diabète de la Seabird Island faisait subir un test de dépistage aux personnes qui ignoraient si elles avaient le diabète en utilisant les taux d'A1c obtenus par prélèvement du sang capillaire au bout du doigt et analysés hors laboratoire selon le système Siemens/Bayer DCA (dichloroacétate) 2000. Les clients se rendaient ensuite dans un laboratoire clinique pour l'épreuve de confirmation des taux d'A1c du sang veineux, de la glycémie veineuse à jeun (GVJ) et de la glycémie veineuse 2 heures après l'ingestion de 75 g de glucose par voie orale (GV2h). Un laboratoire de référence comparait le DCA (dichloroacétate) 2000 et l'Integra 800CTS de Roche à la méthode de référence de l'étude DCCT (Diabetes Control and Complications Trial) du programme NGSP (National Glycohemoglobin Standardization Program).

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1499-2671 © 2015 Canadian Diabetes Association.
http://dx.doi.org/10.1016/j.jcjd.2015.11.003

Résultats : 1) Au laboratoire de référence, le DCA 2000 et l'Integra 800CTS correspondaient très étroitement aux normes de la DCCT. Sur le terrain, le % d'A1c du sang capillaire était biaisé, puisqu'il sous-estimait le % de l'A1c du sang veineux de 0,19 en moyenne ($p < 0,001$). La marge d'erreur du % d'A1c du sang capillaire ajusté au biais était de ± 0,36 dans 95% du temps comparativement à ± 0,27 pour le % d'A1c du sang veineux. 2) Dans la régression linéaire, nous avons observé qu'une GVJ de 7,0 mmol/l et une GV2h de 11,1 mmol/l prédisaient des taux moyens d'A1c du sang veineux se rapprochant de 6,5%, sans biais significatifs.
Conclusions : Les taux d'A1c du sang capillaire hors laboratoire n'avaient pas un aussi bon rendement qu'au laboratoire, mais le biais est corrigible et la marge d'erreur est si petite que les analyses sont utiles sur le plan clinique. Dans cette population, les taux d'A1c du sang veineux ≥6,5% correspondent étroitement aux seuils du GVJ et du GV2h pour diagnostiquer le diabète. L'ajustement sur l'ethnicité du seuil d'A1c du sang veineux n'est pas nécessaire.

Introduction

Since December 2009, the Seabird Island Band (www.seabirdisland.ca) has operated a mobile diabetes clinic serving 70 First Nations bands in the southern mainland of British Columbia, which have a population of 22 435 residing on reserves. The mobile clinic team travels to First Nations communities and provides diabetes-care services recommended by the current Clinical Practice Guidelines (1): focused interview and physical examination (height, weight, blood pressure measurement, vascular and neural foot examination), point-of-care laboratory tests (glycated hemoglobin [A1C] levels, fasting serum lipid profile, serum creatinine, urinary albumin-to-creatinine ratio, estimated glomerular filtration rate), and eye examination (retinal photography, tonometry). A certified diabetes nurse educator provides personal diabetes-management education. The examination record is entered into a web-based information system, then is reviewed by an endocrinologist and an ophthalmologist, and recommendations are sent to the clients' primary care providers. From April 2011 through May 2013, the mobile clinic implemented a pilot program of community-based screening to detect previously undiagnosed diabetes, using finger-prick capillary A1C levels with point-of-care analysis. We compare this A1C measurement method to conventional screening tests. These were the research questions:

How closely do capillary A1C levels agree with venous A1C levels?

Glycated hemoglobin (A1C) can be measured in venous blood or in capillary blood (obtained by finger-prick). Portable point-of-care systems testing A1C levels in capillary blood are very acceptable to clients and are useful in settings where clinical laboratory services are not readily available. However, to diagnose diabetes, the clinical Practice Guidelines specify that A1C levels be measured in venous blood, using a validated assay standardized to the National Glycohemoglobin Standardization Program-Diabetes Control and Complications Trial (DCCT) reference (2). Correlation of capillary A1C levels with venous A1C levels has received only limited study (3). To monitor clients with known diabetes, the Seabird Island mobile diabetes clinic measures capillary A1C levels using the Bayer (Siemens, Munich, Germany) DCA 2000 point-of-care system. We test how closely this capillary A1C level measurement method agrees with the DCCT reference standard directly and with a DCCT-validated venous A1C assay by a commercial clinical laboratory.

In this program's target population, how well do venous A1C levels agree with plasma glucose, for purposes of diagnosing diabetes?

The Canadian Diabetes Association Clinical Practice Guidelines Expert Committee accepts 3 tests to diagnose diabetes: A1C levels, fasting plasma glucose (FPG), and plasma glucose measured 2 hours after a 75 gram oral glucose load (2hPG) during an oral glucose tolerance test (OGTT) (2). A1C-level testing does not require fasting or waiting, so it is more convenient than the other 2 tests. In the general populations of Canada and the United States, any one of A1C ≥6.5%, FPG ≥7.0 mmol/L or 2hPG ≥11.1 mmol/L is considered diagnostic of diabetes (subject to confirmation by repeat of the same test) because all 3 thresholds are independently associated with similar probability of diabetic retinopathy (2,4,5). However, a study in the United States found that American Indian subjects had mean A1C levels 0.36 higher than Caucasian subjects (6.12% vs. 5.76%) after adjusting for plasma glucose measured before and during OGTT (6). This suggests that among American Indian populations, the criterion of A1C levels ≥6.5% would be biased toward overestimating the prevalence of diabetes, and the threshold should be adjusted upward by 0.36 to correct the bias. Among Canadian First Nations populations, the correlation of A1C levels with FPG and 2hPG has received only limited study (7) and, as noted in the 2013 Clinical Practice Guidelines, more research may help to determine whether an ethnicity-specific adjusted A1C threshold is needed (2). The question can be definitively answered only by a study comparing the predictive validities of A1C levels, FPG and 2hPG with respect to the presence of diabetic retinopathy among the Canadian First Nations population. As an exploratory first step, we tested the hypothesis that the 3 thresholds (A1C levels = 6.5%, FPG = 7.0 mmol/L, and 2hPG = 11.1 mmol/L) are inconsistent with each other when applied to a Canadian First Nations population.

Methods

The University of British Columbia Clinical Research Ethics Board reviewed and approved the methods (file H10-02551). All subjects gave informed consent (or assent in the case of minors).

The Seabird Island Band, collaborating with First Nations leaders, community health centres and local healthcare providers, organized diabetes-awareness events in 5 First Nations communities: 4 in the urban-influenced Fraser Valley and 1 in the rural Bella Coola Valley. Each event was a 1-day program about preventing and living well with diabetes. Everyone in the community was invited. There were talks by community leaders, healthcare providers and people with diabetes, with questions and discussions, traditional dances and songs and dinners of traditional foods. These events promoted diabetes awareness, prevention and improved management. They also helped the community to build relationships with healthcare providers and to access resources.

During these events, Seabird Island mobile diabetes clinic nurses offered screening for diabetes to people 10 years of age or older who were not known to have diabetes. The screening test included A1C levels measured in capillary blood collected by finger-prick and analyzed by a DCA 2000 point-of-care system. If A1C levels were ≥5.7%, the nurse directed the person to the nearest BC Biomedical Laboratory specimen-collection point for confirmatory testing (venous A1C levels, FPG and OGTT with 2hPG), with instructions to attend within 1 week and to arrive after fasting. To reduce the travel burden, a phlebotomist visited the Fraser Valley sites to collect venous blood specimens. The Bella Coola Valley site was 4.6 km from the nearest

collection point at the community hospital. Clients who completed confirmatory tests received a food voucher worth $15. Nurses also provided information about risk factors for diabetes and diabetes prevention in a culturally appropriate context. Confirmatory test results were sent to the clients' personal physicians or to the attending physicians at the local community health facility. Persons with diabetes or prediabetes were contacted and offered enrolment into the mobile diabetes clinic program or local community clinic and were referred back to their primary care physicians with recommendations for further follow up.

Anybody who wanted the screening A1C test received it, including some people with known diabetes. They received the A1C test but we excluded their results from data analysis.

Agreement between capillary A1C and venous A1C levels

Canadian External Quality Assessment Laboratory (CEQAL) evaluated the point-of-care DCA 2000 A1C system used by the Seabird Island mobile diabetes clinic and the Roche Integra 800CTS Turbidimetric Inhibition Immunoassay system (Roche Diagnostics, 9115 Hague Road, PO Box 50457, Indianapolis, Indiana, USA) used by BC Biomedical Laboratories. Six standard samples of human whole blood with known A1C content (previously determined by DCCT reference methods) were assayed 3 times each by the DCA 2000 and Integra 800CTS systems. Each of the 6×3=18 trials thus produced 3 A1C values: A1C measured by DCA 2000, A1C measured by Integra 800CTS and the DCCT reference value. Ideally, the 3 values should agree. To test this, at each trial we calculated differences between pairs of A1C values (i.e. DCA 2000 minus DCCT, Integra 800CTS minus DCCT, and DCA 2000 minus Integra 800CTS).

Studying these differences, we assessed disagreement among measurement methods. There are 2 types of disagreement: bias and variability. Bias is the systematic tendency of a test to produce results higher or lower than the reference method to which it is compared. We calculated bias as the mean of the differences between the test and the reference among 18 trials. Variability is the tendency of a test to produce randomly varying results when repeated. We calculated variability as the standard deviation of the differences between the test and the reference among 18 trials. We tested the statistical significance of the bias by paired t test, estimating the 2-sided probability that the mean difference is zero.

Among persons who had confirmatory tests, we assessed disagreement between capillary A1C (DCA 2000, operated in the field by the Seabird Island mobile diabetes clinic) and venous A1C (Integra 800CTS, operated by BC Biomedical Laboratories). We calculated the difference between each person's screening A1C level and confirmatory A1C level (i.e. capillary A1C minus venous A1C). We calculated bias as the mean and variability as the standard deviation of the differences in the tested persons. We tested statistical significance of the bias by paired t test. If the bias was statistically significant ($p<0.05$, 2-sided), we regressed venous A1C as a linear function of capillary A1C and then used the regression equation to correct the bias by adjusting each person's capillary A1C levels.

Agreement between venous A1C levels and plasma glucose

Among people who had confirmatory tests, we regressed venous A1C levels as a linear function of FPG and of 2hPG. We used the regression equations to predict the mean venous A1C levels associated with the glycemic thresholds for diabetes (i.e. FPG = 7.0 mmol/L, 2hPG = 11.1 mmol/L). We considered how closely these predicted mean venous A1C levels agreed with the generally accepted threshold to diagnose diabetes (i.e. A1C = 6.5%).

Results

Table 1 shows the ages, genders and geographic distributions of the 258 people screened and the summary statistics and frequency distribution of their capillary A1C measurements. The mean capillary A1C level was 5.5% (95% CI: 5.4% to 5.6%). The mean capillary A1C levels increased with age, but we found no statistically significant differences between males and females or between residents of the Fraser Valley and residents of the Bella Coola Valley. Of 258 people, 60 (23.3%) had capillary A1C levels ≥5.7% and were invited to have confirmatory tests. Among the 9 subjects younger than 18 years of age, none had capillary A1C levels ≥5.7%. Seven invitees were subsequently excluded due to previously diagnosed diabetes; 24 refused or did not go; and follow up was incomplete in 4 cases. The remaining 25 invitees had confirmatory tests. As shown in Table 1, the 60 invitees had an older age distribution than the 258 screened (as expected, given their higher capillary A1C measurements), but the 2 groups were similar in geographic and gender distribution. The 25 who had confirmatory tests were similar to the 60 invitees in age, gender and geographic distribution, so they appear to be a representative sample.

Agreement between capillary A1C and venous A1C levels

Table 2 shows results of CEQAL's evaluation of the point-of-care DCA 2000 A1C system used by the Seabird Island mobile diabetes clinic and the Integra 800CTS system used by BC Biomedical Laboratories. The DCA 2000 and the Integra 800CTS systems agreed very closely with the DCCT reference standard. Their mean A1C%

Table 1
Diabetes screening test results by site, age and gender categories

	All screened subjects								A1C ≥5.7%		Confirmatory tests	
	n	%	A1C % mean	A1C % SD	L95 CL mean	U95 CL mean	A1C % ≥5.7	A1C % ≥6.5	n	%	n	%
Total	258	100.0%	5.7	3.5	5.3	6.1	23.6%	4.3%	60	100.0%	25	100.0%
Fraser Valley	188	72.9%	5.4	0.6	5.4	5.5	21.8%	3.2%	41	68.3%	18	72.0%
Bella Coola	70	27.1%	5.7	1.5	5.3	6.0	27.1%	5.7%	19	31.7%	7	28.0%
Female	176	68.2%	5.5	1.0	5.3	5.6	22.2%	3.4%	39	65.0%	16	64.0%
Male	82	31.8%	5.5	0.7	5.4	5.7	25.6%	4.9%	21	35.0%	9	36.0%
Age 10–17	9	3.5%	5.2	0.3	5.0	5.4	0.0%	0.0%	0	0.0%	0	0.0%
Age 18–24	36	14.0%	5.3	0.4	5.1	5.4	5.6%	2.8%	2	3.3%	0	0.0%
Age 25–34	59	22.9%	5.3	0.3	5.2	5.4	6.8%	0.0%	4	6.7%	2	8.0%
Age 35–44	50	19.4%	5.4	0.5	5.3	5.5	18.0%	2.0%	9	15.0%	4	16.0%
Age 45–54	43	16.7%	5.7	1.2	5.3	6.0	32.6%	4.7%	14	23.3%	6	24.0%
Age 55+	45	17.4%	6.0	1.4	5.6	6.4	64.4%	11.1%	29	48.3%	13	52.0%
Age unknown	16	6.2%	5.5	0.8	5.0	5.9	12.5%	6.3%	2	3.3%	0	0.0%

L95 CL, Lower 95% confidence limit of A1C% mean; U95 CL, Upper 95% confidence limit of A1C% mean.

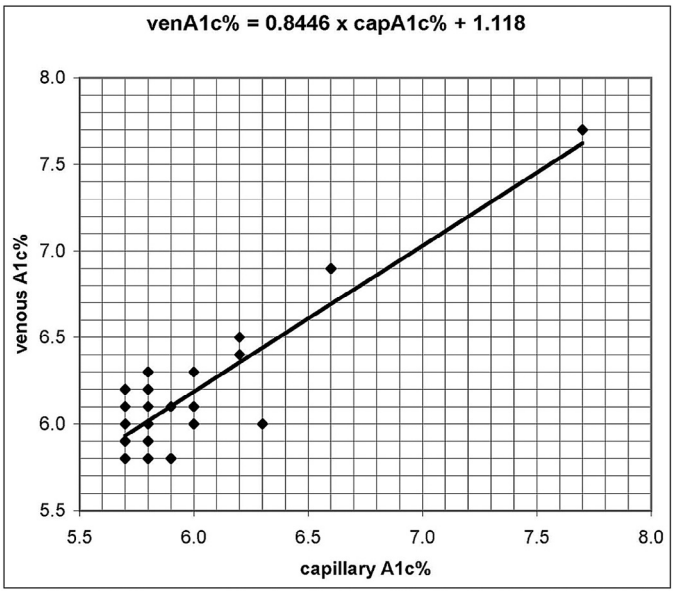

Figure 1. Regression line of venous A1C as a function of capillary A1C levels.

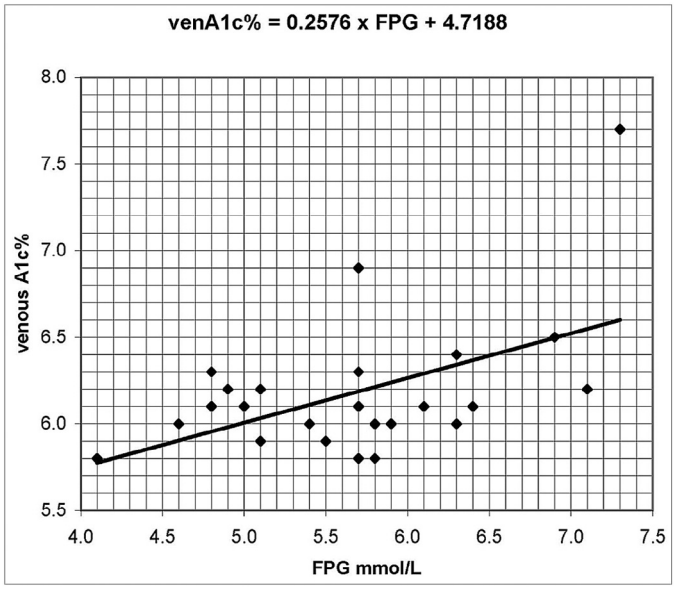

Figure 2. Regression line of venous A1C as a function of fasting plasma glucose test.

differences with DCCT (–0.05 and –0.01, respectively) were very small and not statistically significantly different from zero (p=0.262 and p=0.671, respectively). The DCA 2000 also agreed very closely with the Integra 800CTS (mean A1C% difference was –0.03; p=0.255).

In the field, between capillary A1C (DCA 2000, operated in the field by the Seabird Island mobile diabetes clinic) and venous A1C (Integra 800CTS, operated by BC Biomedical Laboratories) the mean A1C% difference was –0.19, and this bias was statistically significant (p<0.001). The standard deviation of the capillary-to-venous difference (0.20) was also higher in the field than in the laboratory (0.12, DCA 2000 to Integra 800CTS difference). The regression line of venous A1C as a linear function of capillary A1C is shown in Figure 1: venA1C %=0.8446×capA1C% + 1.118 (R^2=0.784; p<0.001). Using this equation to adjust capillary A1C, the mean difference between adjusted capillary A1C and venous A1C becomes zero (Table 2). The adjustment corrects the bias, but the variability remains almost unchanged: SD=0.19 (adjusted capillary-to-venous difference), compared to SD=0.20 (capillary-to-venous difference).

To assess the practical significance of the variability of the capillary A1C test as it is performed in the field, we calculated the margin of error (ME) as plus or minus (±) 1.96×SD, 95% of the time. With venous A1C as the reference standard, the ME of the capillary A1C% measurement is ±0.39. After correcting the bias, the ME of adjusted capillary A1C% is ±0.36. In comparison, with the DCCT standard as the reference, the ME of venous A1C% is ±0.27.

Agreement between venous A1C levels and plasma glucose levels

Twenty-five people had confirmatory tests; Figure 2 shows the regression line of venous A1C levels as a linear function of FPG: venA1C %=0.2576×FPG+4.7188 (R^2=0.257; p=0.010). FPG levels of 7.0 mmol/L predicted a mean venous A1C level of 6.52% (95% CI for the mean: 6.23% to 6.82%). Figure 3 shows the regression line of venous A1C levels as a linear function of 2hPG: venA1C %=0.0972×2hPG+5.5335 (R^2=0.414; p=0.001). The 2hPG of 11.1 mmol/L predicted a mean venous A1C of 6.61% (95% CI for the mean: 6.35% to 6.87%). These predictions are close to and not statistically significantly different from 6.5%.

Discussion

Laboratory scientists typically measure variability among repeated measurements of the same analytic sample under the same conditions. We measured variability among attempts to confirm a test with a reference standard test repeated in multiple subjects. We suggest that our method is more relevant for clinicians who are interpreting test results.

We do not know why the DCA 2000 system did not agree as well with the confirmatory tests in the field as in the reference laboratory. The A1C testing by the Seabird Island mobile diabetes clinic is

Table 2
Agreement among A1C measurement methods

Test		Reference		Bias (test reference)				
Method	Mean A1C %	Method	Mean A1C %	n	Mean A1C %	SD A1C %	p[e]	ME[f] ±A1C %
DCA 2000[a]	7.68	DCCT standard	7.73	18	–0.05	0.17	0.262	0.34
Integra 800CTS[a]	7.71	DCCT standard	7.73	18	–0.01	0.14	0.671	0.27
DCA 2000[a]	7.68	Integra 800CTS[a]	7.71	18	–0.03	0.12	0.255	0.24
Capillary[b]	5.99	Venous[c]	6.18	25	–0.19	0.20	0.000	0.39
Adjusted capillary[d]	6.18	Venous[c]	6.18	25	0.00	0.19	1.000	0.36

DCCT, Diabetes Control and Complications Trial.
[a] Evaluated by Canadian External Quality Assessment Laboratories.
[b] DCA 2000, operated by Seabird Island mobile diabetes clinic.
[c] Integra 800CTS, operated by BC Biomedical Laboratories.
[d] (Adjusted capillary A1C %)=0.8446×(capillary A1C %)+1.118.
[e] Probability (2-sided, paired t test) of null hypothesis that mean bias is zero.
[f] Margin of error of the test method (A1C %): ±1.96×SD, 95% of the time.

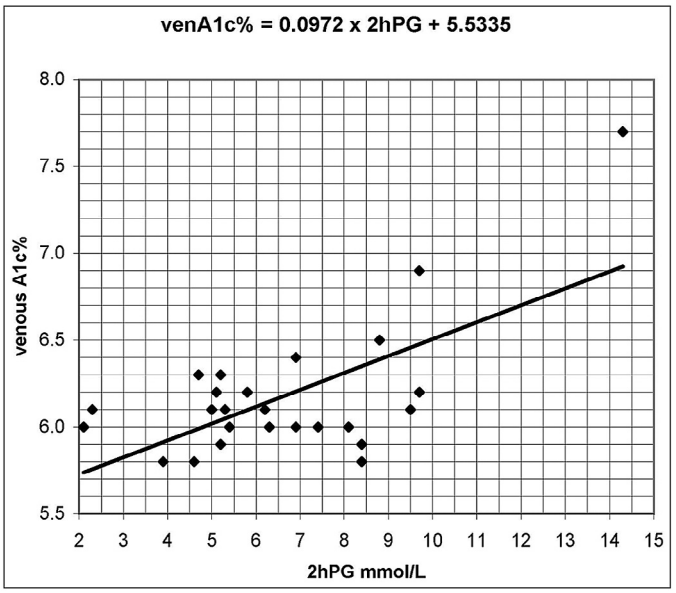

Figure 3. Regression line of venous A1C as a function of 2-hour plasma glucose test.

monitored by a quality-management program developed by CEQAL. This program incorporates 2 levels of DCCT reference A1C value-assigned human whole blood samples. Quality control samples are analyzed prior to patient testing to confirm method performance and A1C test accuracy. This ensures that preanalytic error due to transportation and equipment set-up are not factors and that reagent integrity and the analytic process itself have not been compromised. Because A1C is expressed as a percentage of total hemoglobin, rather than as a concentration, preanalytic blood collection is not a source of error with this test (assuming that the collected amount of hemoglobin is above the detection threshold for the test). It is possible that the confirmatory A1C test method was more variable in mundane use than when evaluated in the reference laboratory. The bias and variability that we measured in the field included all the real-world sources of variability that we encountered. Our results suggest that every program should evaluate its own testing methods in the field as well as in the laboratory. Other programs may find bias and variability different from our results.

Limitations

Our findings suggest that in the Seabird Island client population venous A1C ≥6.5% is an appropriate threshold for diagnosing diabetes, agreeing with the generally accepted thresholds based on FPG and 2hPG (5) and not needing adjustment. Our target population may not be representative of all Canadian First Nations populations.

We had planned to perform categoric 2×2 table and receiver operating characteristic curve analyses to determine the optimal A1C threshold and associated sensitivity, specificity, positive predictive value and negative predictive value of capillary A1C as a screening test for diabetes, as defined by generally accepted venous A1C, FPG and 2HPG diagnostic thresholds. Unfortunately, our attained sample size (25 clients with confirmatory tests) was not large enough to support such analyses.

Although we found numerical consistency among the venous A1C, FPG and 2hPG thresholds for diabetes, we cannot say whether the A1C threshold would predict the same likelihood of diabetic retinopathy among First Nations people as it would among the general population of Canada. Logically, the next step in our research, which could be done with data already collected by Seabird Island and other First Nations mobile diabetes clinics in British Columbia, would be to test capillary A1C levels as predictors of the presence of diabetic retinopathy.

Conclusions

We identified a bias (underestimation of about 0.19) in the capillary A1C% measurements. Arithmetic adjustment (multiply by 0.8446, then add 1.118) corrects the bias. The margin of error of the adjusted capillary A1C% (±0.36, 95% of the time) is only modestly larger than that of venous A1C% by a commercial laboratory (±0.27). We found capillary A1C levels to be clinically useful, but other programs should validate their own testing systems in the field as well as in the laboratory.

In the Seabird Island client population, venous A1C ≥6.5% is appropriate to diagnose diabetes and does not need adjustment for ethnicity. This might not apply to all Canadian First Nations populations.

Acknowledgements

This work was funded by Kloshe Tillicum, Network Environments for Aboriginal Health Research, British Columbia and Yukon Territory. The authors thank Dr. Robert G. Fox for providing subsequent medical care to study subjects.

Author Disclosures

Carolyne Neufeld is employed by the Seabird Island Band.

Author Contributions

JMF conceived and designed the study and edited the manuscript; AJ participated in the design of the study, performed statistical analysis and drafted the manuscript; DWS participated in the design of the study, performed statistical analysis and edited the manuscript; SS edited the manuscript; CN facilitated the conduct of the study and edited the manuscript; KGD participated in the design of the study and edited the manuscript.

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