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Utility of point-of-care vs reference laboratory testing for the evaluation of glucose levels

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Abstract

Aims—To assess the level of agreement between point-of-care and laboratory reference glucose values in defining glycaemic status.

Methods—We analysed 1292 overweight/obese, non-institutionalized participants, aged 40–65 years, in the San Juan Overweight Adults Longitudinal Study. Fasting venous blood glucose was determined using a point-of-care Bayer Contour Blood Glucose Meter and by Vitros System 250 instrument (laboratory). American Diabetes Association thresholds were used to classify participants into normoglycaemia (< 5.6 mmol/l), prediabetes (5.6 to 6.9 mmol/l), or diabetes groups (≥ 7 mmol/l).

Results—Bland–Altman plot analysis showed a slope of 0.04 ($P=0.002$) for the regression between the mean difference and the average of the two methods. The slopes were significantly different from zero among people with normoglycaemia ($\beta=-0.57$, $P<0.001$), and prediabetes ($\beta=-0.75$, $P<0.001$) but not among people with diabetes ($\beta=-0.02$, $P=0.68$). When the prediabetes and diabetes groups were merged into one group, the slope was 0.01, and the glucose values remained similar using the two methods ($P=0.76$).

Conclusion—Point-of-care blood glucose measurement may be useful to screen people with diabetes, and to assess glucose among individuals with diabetes where blood can be drawn, but laboratory tests are unavailable or untimely.

Introduction

Many different biochemical tests have been evaluated for the screening and diagnosis of diabetes mellitus [1,2]. These tests include urine glucose, plasma venous glucose (both fasting and postprandial), capillary glucose, and HbA_{1c} measurements from whole blood. The purpose of these tests is to identify asymptomatic individuals or to confirm any doubt

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regarding diagnoses among those who have a high likelihood of Type 2 diabetes owing to the presence of established risk factors for development of the disease [3,4].

Over the past few decades, diagnostic technologies have become cheaper, easier to handle, and in some cases more accurate, thus enabling physicians to make informed decisions about treatment, specialty referral and hospital admission [5]. There is a wide range and growing number of point-of-care and handheld devices or portable analysers, which provide rapid 'on-site' glucose levels to help maintain glycaemic control and to detect acute hypoglycaemic and hyperglycaemic conditions [6] through glucose oxidase or glucose 1-dehydrogenase methodology [7]. In addition to their current use by patients, these may have the potential to improve outcomes in primary care by optimizing clinical decisions, reducing referrals, reducing hospitalization time, improving efficiency of care, and decreasing costs [8]. The conversion of point-of-care glucose values from fresh capillary blood and from venous whole-blood samples (e.g. tests used by healthcare professionals in clinical or hospital settings) to laboratory tests are subject to random measurement errors [9–11]. The American Diabetes Association (ADA) recommended an acceptable error range of up to 15% between the values obtained by glucose meter to be tested and those obtained by the laboratory reference method, which was modified subsequently to a maximum error range of up to 5% [12]. Previous studies have demonstrated favourable overall performance of various point-of-care glucose meters in determining glucose values in venous blood samples as compared to laboratory reference values in hospital settings [10,11,13–16]; however, data on point-of-care glucose meter validity according to glycaemic status are limited; therefore, the objective of the present study was to assess the level of agreement of point-of-care measures of venous whole blood glucose with laboratory glucose measures in defining glycaemic status.

Methods

Study sample

Overweight and obese non-institutionalized individuals were invited to participate in the San Juan Overweight Adults Longitudinal Study (SOALS). Participants were residents of Puerto Rico and were eligible if they were: 1) free of previously diagnosed diabetes; 2) aged between 40 and 65 years; and 3) overweight or obese [body mass index (BMI) of at least 25.0 kg/m²]. Participants were excluded if they were unable to complete the study procedures. Additional detailed information on the study's exclusion criteria is provided in our previous publications [17]. The Institutional Review Board at the University of Puerto Rico approved the study. All participants provided signed consent forms prior to any study procedures.

Of 2626 individuals screened for eligibility, 695 did not meet the inclusion criteria and were excluded. Of 1931 eligible potential participants, 1610 agreed to participate in the study, and 1451 actually attended their arranged visits at the Puerto Rico Clinical and Translational Research Consortium (PRCTRC) centres. At this visit, 100 participants were excluded after further assessment and confirmation of the eligibility criteria prior to the start of the study procedures. Of the remaining 1351 participants, 59 had missing point-of-care glucose data and were excluded. Thus, the final sample size consisted of 1292 diabetes-free participants.

Participants were asked to fast for 10 h prior to their appointments at the centre. Well-trained phlebotomist nurses at the PRCTRC centres performed the blood draw between 07:00 and 09:30 h using a standard protocol and silicone-coated sterile Vacutainer collection tubes (BD Vacutainer®, Becton Dickinson and Company, Franklin Lakes, NJ, USA).

Point-of-care test

Immediately after the blood collection, a drop of the whole-blood sample (i.e. before blood clotting) from the 10-mL serum collection tube was used to measure glucose once using a Bayer Contour blood glucose meter (Bayer HealthCare LLC/Ascensia Diabetes Care, Basel, Switzerland) [18]. The test was performed by one trained researcher (J.L.V.). Participants were considered to be free of Type 2 diabetes if the glucose meter reading was within the normal (<5.6 mmol/l) to prediabetic (5.6 to 6.9 mmol/l) range. If a participant was found to be in the range for diabetes based on fasting glucose (≥ 7 mmol/l), a referral for further testing was provided.

Laboratory fasting glucose reference

After removing the drop of whole blood sample for the glucose meter, the tube was gently inverted five times. Blood was allowed to clot for 30 min and then was centrifuged at high speed for 15 min. After centrifugation, a barrier was formed separating cells from serum. Serum was then collected, and the glucose concentration was immediately measured using an enzymatic colorimetric assay instrument with the Vitros System 250 (VS 250), with diffraction spectrometry technology (coefficient of variation for intra-assay = 1.21%; inter-assay = 3.06%). The 'Vitros GLU' slide was used. A drop of 10- μ l serum sample is placed on the slide. A red dye is produced after sequential chemical reactions occur. The intensity of the dye is then measured by reflected light. The duration of the procedure is ~5 min at 37°C (Vitros Chemistry Products. Test methodology. Vitros GLU slides. Part No. MP2-8. CAT No.803 3052).

Serum glucose level was measured once, and the measurements across the samples were performed by a well-trained laboratory technician. ADA thresholds for fasting serum glucose were used to determine glycaemic status: normoglycaemia if participants had fasting serum glucose levels < 5.6 mmol/l; prediabetes for levels 5.6–6.9 mmol/l; and diabetes for levels ≥ 7 mmol/l [19].

Statistical analysis

Baseline characteristics of the study population according to the glycaemic status groups were described using absolute frequencies and percentages or means and standard deviations. The percentage in concordance in glycaemic status between the two methods (positive by point-of-care among those who are positive by the laboratory test) was assessed. The overall concordance of the point-of-care device values against the laboratory measures K statistic, as well as the concordance of the two methods after stratification into glycaemic status subgroups, were assessed with the aid of Bland–Altman graphical analysis [20]. The Bland–Altman plots of differences in fasting glucose between the two methods against the overall mean fasting glucose obtained by both methods were used to evaluate any possible relationship between measurement error and the true value. Although we did not know the

true value, we used the overall mean of the two measurements as the best estimate; thus, the differences between the two measurements was first computed, and normality was assessed by histogram and Shapiro–Wilk test. The overall mean of point-of-care and laboratory measures were computed (*x*-axis) and plotted against the difference between these two measurements (*y*-axis). Horizontal lines were drawn at the mean difference of the two methods and at the limits of agreement defined by the mean difference ± 1.96 (standard deviation of the difference). A regression line was drawn to visually depict this relationship [21]. We used STATA version 13 for our statistical analysis (StataCorp LP, College Station, TX, USA).

Results

A total of 72% of the participants were women, 65% were obese (mean BMI 33.5 ± 6.3 kg/m²), and the mean age was 50.5 ± 6.7 years (Table 1). Mean glucose levels were 5.4 ± 1.3 mmol/l using laboratory measurement and 5.4 ± 1.3 mmol/l using the point-of-care glucose meter. When participants were classified by glycaemic status, those in the group with prediabetes were older than those in the normoglycaemia or diabetes groups. The diabetes group had the highest percentage of men as compared to the other groups; however, BMI values appeared to be evenly distributed throughout the three groups. The mean glucose levels using laboratory reference were 5.4 ± 1.3 mmol/l, 6.0 ± 0.4 mmol/l and 6.0 ± 0.4 mmol/l in the normoglycaemia, prediabetes and diabetes groups, respectively, while the corresponding values using the glucose meter were 5.2 ± 0.5 mmol/l, 5.9 ± 0.6 mmol/l and 9.4 ± 3.2 mmol/l, respectively.

Table 2 shows the classification of participants' glycaemic status by different methods. Approximately 56% of participants were classified as having normoglycaemia, 16% as prediabetes, and 4% as Type 2 diabetes, based on both point-of-care and laboratory methods. Approximately 16% of participants in the normoglycaemia group were misclassified as having prediabetes using the point-of-care meter, while ~7% of participants with prediabetes were misclassified as normoglycaemic by the point-of-care meter. By contrast, only 0.5% of participants with prediabetes and 0.6% of participants with diabetes were misclassified as having diabetes and prediabetes by the point-of-care meter, respectively.

The overall percent concordance and κ statistic between the point-of-care and laboratory reference methods were 75% and 0.47 (95% CI 0.46–0.50), respectively. The percent concordance varied by glycaemic status and was highest in the group with diabetes (normoglycaemia: 77.3%; prediabetes: 66.5%; diabetes: 85.5%). The normality distribution of the overall mean glucose difference between the two methods was assessed, and the normality assumption appeared reasonable.

The overall mean glucose difference was 0.1 ± 0.5 mmol/l, and the limits of agreement were -1.0 , 1.2 (Fig. 1a). Although the slope of the regression line was 0.04, this difference was still statistically significant ($P=0.002$), suggesting a possible association between the mean difference and mean average level of fasting glucose of the two methods.

When stratifying the data by glycaemic status, mean point-of-care glucose values were higher than the mean laboratory values by 0.2 mmol/l for the group with normoglycaemia, and lower by 0.1 mmol/l for the prediabetes and by 0.4 mmol/l for the diabetes group (Fig. 1b–d). The limits of agreements (see definition above) of the mean differences were as follows: normoglycaemia: $-1.1, 0.7$ mmol/l; prediabetes: $-1.0, 1.2$ mmol/l; and diabetes: $-1.6, 2.4$ mmol/l. The slopes of the regression lines were significantly different from zero in the normoglycaemia ($\beta = -0.57, P < 0.001$) and prediabetes groups ($\beta = -0.75, P < 0.001$; Fig. 1b,c); however, there was no association in the group with diabetes ($\beta = -0.02, P = 0.68$; Fig. 1d). When the prediabetes and diabetes groups were merged into one group (Fig. 1e), the mean glucose difference was 0.2 ± 0.7 mmol/l, and the limits of agreement were $-1.2, 1.5$ mmol/l. The slope became $\beta = 0.01$, and the point-of-care glucose values remained comparable to those of the laboratory reference test ($P = 0.76$).

Because the normoglycaemia group was large ($n=929$), we categorized this group into tertiles to further examine the variations across the tertiles in the measures of interest of distributions of the glucose values and associations (data not shown). The means of the glucose difference (limits of agreement) between the two methods were -0.3 ($-1.1, 0.5$) mmol/l; -0.2 ($-1.1, 0.7$) mmol/l; and -0.1 ($-1.1, 0.8$) mmol/l in the first, second and third tertile groups, respectively. The slopes of the regression lines consistently showed statistically significant associations between the mean difference and mean average level of fasting glucose of the two methods across the tertiles (first tertile: $\beta = -1.1, P < 0.001$; second tertile: $\beta = -1.8, P < 0.001$; and third tertile: $\beta = -1.7, P < 0.001$).

Discussion

We found significant differences between the point-of-care and laboratory glucose values, especially among participants with normoglycaemia and prediabetes, but no difference among participants with diabetes or merged prediabetes and diabetes. These findings are different from previous recent studies that showed similar measurements for the two methods [10,11,14,22]. Nonetheless, searching the available literature for a comparison with the present results was difficult because most studies on the accuracy of the point-of-care devices compared capillary (finger stick) glucose measurements with the glucose measures, and were performed in inpatient settings [23]. The present results may be affected by the fact that glucose meters are calibrated to account for differences between capillary blood and venous blood.

Similarly to the present study, some studies suggest there is high variability in the glucose differences in very low (i.e. hypoglycaemic) ranges or for low glucose concentration (<5.6 mmol/l). There was no substantial difference between our findings in the normoglycaemia group and findings when this group was divided into tertiles. By contrast, previous studies reported decreased accuracy with very high glucose concentration (>5.6 mmol/l) [11,24–26]. The different findings among the studies might be related to differences in study populations.

The limits of agreement for the mean glucose differences in the present study differed from most previous findings and from the International Organization for Standardization (ISO)

15197: 2013 requirement for an acceptable device performance, which stipulates a minimum error range of the test results of within 15% if the blood glucose concentration is ≥ 5.55 mmol/l and within 0.83 mmol/l for blood glucose concentrations < 5.55 mmol/l [27]. This difference could be attributable to our use of serum glucose measures rather than plasma for reference and/or the difference in the laboratory reference method (VS250 in the present study). For instance, the study by Wei *et al.* [11] or by Bedini *et al.* [14] used whole-blood samples with anticoagulants (plasma) for their reference. Nevertheless, all the measurements, except two observation points (see graph) were within the limits of agreement among the diabetes group, even though these limits were larger than those for the normoglycaemia or prediabetes groups separately. In fact, there is no perfect standard to describe the performance of the point-of-care device. The ISO and the ADA standard have their own drawbacks [28]. In addition, the assessment of point-of-care performance should not depend only on the analytical accuracy of that instrument, but also on the clinical outcome performance [28].

Agreement between the point-of-care and laboratory reference values differed between the prediabetes and diabetes groups; however, when we merged the prediabetes and diabetes groups into one group, glucose measures between the point-of-care and laboratory reference methods remained comparable. This finding could be explained by the increase in sample size after merging the group, but a greater number of point observations were outside the limits of agreement (Fig. 1e). Nonetheless, this finding is similar to those of previous studies, although many of them, as described above, showed some discrepancies, with higher variability for high glucose concentrations.

Our more robust findings for higher glucose concentrations support the importance of evaluating the validity of tests within subgroups defined by glycaemic status; in other words, observations regarding the performance of the point-of-care device in the prediabetes group could have been missed, if the prediabetes and diabetes groups had been merged into one, as in previous studies.

Point-of-care measurements may misclassify a person with normoglycaemia as having prediabetes or diabetes [9]. Hence, people intending to extend the use of the point-of-care device beyond its currently intended use, as a screening tool, particularly to classify diabetes status, should use the point-of-care values carefully, especially when the value is close to 7 mmol/l. Overall, when point-of-care device values are used to screen for or to determine if a person has diabetes and the value obtained is far from 7 mmol/l, the point-of-care meter may be a valid and practical instrument, and useful when laboratory results are not easily available and/or results are needed quickly to make a time-sensitive decision. In a clinical setting where there is a need to assess glucose in a time-sensitive manner or to decrease the time to treatment decisions (such as insulin dosing decisions), point-of-care instead of laboratory testing will be the best method, but only after accounting for the precision of the device, as most point-of-care devices were never intended to be used for treatment situations. The precision of point-of-care values is also impaired by inappropriate use of the devices: mechanical stress applied to the strips, failure to clean the site before testing, dirty meters, and sample issues such as specimen clots, bubbles, failure to use an adequate amount of blood in the test, and failure to calibrate the devices [29]. Based on their high

validity in detecting diabetes and the limitations of point-of-care methods, point-of-care meters may have some utility in screening for diabetes among high-risk groups such as overweight/obese individuals, in settings where laboratory methods are not available or practicable.

Biological factors may adversely affect the performance of devices. While laboratories usually use plasma to measure blood glucose, most home glucose meters use whole blood. It is important to account for the fact that glucose levels differ depending on the sample source, with arterial concentrations being ~0.3 mmol/l higher than capillary concentrations and ~0.6 mmol/l higher than venous concentrations. Haematocrit levels affect the flow of red blood cells and oxygen onto the reagent test strips where glucose and oxygen react with the enzymes on the strip [30–33]. Lower than normal haematocrit levels can provide falsely high blood glucose results, while higher than normal levels can underestimate the glucose concentrations. This can be clinically relevant in patients with marked anaemia as a result of end-stage renal disease. The ADA and WHO classification is based on plasma glucose level [34]; however, serum is often used instead of plasma, and plasma and serum glucose showed similar levels [35].

We examined the use of only one device, but there are several commercially available brands, and types within each brand that use different tests/technology to measure glucose levels. Additional limitations of the study that need to be considered when interpreting our findings include the one-time measurement of glucose concentration using the point-of-care device. The study was designed to assess the potential bi-directional association between periodontal disease and early stage of Type 2 diabetes development; therefore, the study did not include repeated measures that may be used for clinical diagnosis, which would have enabled us to assess the level of agreement between point-of-care and laboratory reference glucose by glycaemic status more accurately. In addition, our study population consisted only of overweight and obese individuals, which could limit the generalizability of our findings. Nonetheless, diabetes is uncommon in individuals of normal weight. Our study provides detailed fasting glucose measurements from both point-of-care and laboratory methods in an adult Hispanic population, and offers a large database permitting the assessment of level of agreement according to glycaemic status.

Future studies reproducing our findings but using standard plasma glucose measurement would be worth conducting. Future testing should also be carried out in conditions that mimic actual clinical practice to verify the clinical accuracy of the devices [36]. In future studies, it might be best to include all participants (with and without physician-diagnosed diabetes) in order to have a sample ranging from people without any glucose abnormalities to those who have severe diabetes, which might affect the point-of-care device readings.

In summary, the present study supports the usefulness of point-of-care measurements to determine glucose values among people with diabetes as the measures were similar to those obtained by laboratory reference tests only in this sub-group, and not among individuals with normoglycaemia or prediabetes. Hence, point-of-care measures for glucose values, because of their attractive features (simple handling, rapid results and cost-efficiency), may be considered in cases where there is capability of drawing venous blood and where

traditional laboratory blood tests are not easily available. This can help empower people living in remote areas, such as in developing countries and poor communities, to screen for and potentially prevent diabetes and health-related issues. Point-of-care may also serve as a tool for healthcare providers when faster results are needed to make decisions during clinical emergencies.

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What's new?

- It has been suggested that point-of-care glucose meters are comparable to laboratory reference testing in terms of capillary and venous whole-blood glucose measurements.
- Data on point-of-care glucose meter performance according to glycaemic status are limited.
- The present study supports the usefulness of point-of-care testing to determine glucose values among individuals with diabetes, but not among individuals with normoglycaemia or prediabetes.
- Point-of-care testing may be used in a setting where traditional laboratory blood tests are unavailable to screen for and potentially prevent diabetes and related conditions.

FIGURE 1.

Bland–Altman difference plot of paired glucose measurements (point-of-care glucose and laboratory reference glucose) across glycaemic status (a) overall ($N = 1292$), (b) in the normoglycaemia group ($n = 929$), (c) in the prediabetes group ($n = 301$), (d) in the diabetes group ($n = 62$) and (e) in the merged group with prediabetes or diabetes ($n = 363$).

Table 1

Baseline characteristics of participants, stratified by American Diabetes Association glycaemic status ($n=1292$)

		ADA glycaemic status		
	Overall <i>N</i> = 1292	Normoglycaemia <i>n</i> = 929	Prediabetes <i>n</i> = 301	Diabetes <i>n</i> = 62
Age, years	50.5 ± 6.7	49.9 ± 6.6	52.0 ± 7.0	50.9 ± 6.2
Men, <i>n</i> (%)	28.1	24.4	34.6	51.6
BMI, kg/m ²	33.5 ± 6.3	33.3 ± 6.3	34.0 ± 6.4	33.9 ± 5.9
Laboratory glucose, mmol/l	5.4 ± 1.3	5.0 ± 0.3	6.0 ± 0.4	9.8 ± 3.1
Point-of-care glucose, mmol/l	5.5 ± 1.3	5.2 ± 0.5	5.9 ± 0.6	9.4 ± 3.2

ADA, American Diabetes Association.

Values are mean ± SD unless otherwise indicated.

Table 2

Point-of-care vs laboratory reference diabetes classification according to American Diabetes Association fasting glucose thresholds

Reference	Normoglycaemia	Prediabetes	Diabetes	Total
Point-of-care				
Normal	718 (77.3)	95 (31.6)	1 (1.6)	814
Prediabetes	211 (22.7)	200 (66.5)	8 (12.9)	419
Diabetes	0 (0)	6 (2.0)	53 (85.5)	59
Total	929	301	62	1,292

$\kappa = 0.47$ (95% CI 0.46–0.50; $P < 0.001$).