AGREEMENT BETWEEN HEMOCUE AND GLUCOSE OXIDASE METHODS FOR BLOOD GLUCOSE MEASUREMENT IN A FIELD WORK STUDY OF DIABETES: THE COMCAAC PROJECT

CONCORDANCIA ENTRE HEMOCUE Y GLUCOSA OXIDASA EN EL ANÁLISIS DE LA CONCENTRACIÓN DE GLUCOSA SANGUÍNEA EN UNESTUDIO DE DIABETES: EL PROYECTO COMCÁAC

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RESUMEN

Los medidores de glucosa se utilizan para ayudar al profesional de la salud a monitorear y detectar alteraciones de la glucosa sanguínea (GS). El objetivo fue comparar la técnica de HemoCue (HC) versus glucosa oxidasa (GOx) para la medición de GS utilizando 368 mediciones de GS por ambos métodos. Se utilizaron gráficos de Bland & Altman, prueba de t-pareada y regresión lineal para su comparación. Se encontró concordancia entre los métodos en la mayoría de los niveles de glucosa, excepto a concentraciones de glucosa ≥ 6.993 mmol / L. El analizador de glucosa HC es bueno para su uso en estudios de campo ya que es técnicamente fácil y requiere muy poco mantenimiento; sin embargo, se recomienda tener especial cuidado con aquellas personas cuyos valores de glucosa están dentro del límite del diagnóstico de diabetes ya que, con el método HC, existe el riesgo de clasificar erróneamente a las personas que ya tienen diabetes como no diabéticas. Por lo tanto, dada la importancia de conocer los valores reales de los niveles de glucosa en este grupo de personas para un diagnóstico preciso, se recomienda considerar un análisis posterior con el método GOx para corroborar el resultado.

Palabras clave: Glucosa sanguínea, HemoCue, Glucosa Oxidasa.

ABSTRACT

To monitor and detect blood glucose (BG) abnormalities, health professionals use glucose meters. The study's objective was to compare HemoCue (HC) versus glucose oxidase (GOx) for the measurement of BG using 368 measurements of BG by both methods. Bland & Altman graphs, paired t-test and linear regression were used to compare the methods. Concordance was found between the methods in most glucose levels, except at glucose concentrations ≥ 6.993 mmol / L. HC glucose analyzer is good for use in field studies because it is technically easy and requires very little maintenance; however, it is recommended to take special care with people whose glucose values are within the limit of the diagnosis of diabetes, since with the HC method there is a risk of misclassifying people who already have diabetes, as non-diabetics. Therefore, given the importance of knowing the actual values of glucose levels in this group of people for an accurate diagnosis, considering a subsequent analysis with the GOx method to corroborate the result is recommended.

Key words: Blood glucose, HemoCue, Glucose Oxidase.

INTRODUCTION

Type 2 diabetes is considered a major global public health problem, so it is important to study its prevalence in order to generate policies aimed at the prevention and control of the disease. To achieve this objective, it is necessary to have diagnostic and monitoring tools that allow accurate results obtained reliably and quickly, which has become the main objective of various studies (Reach y Wilson, 1992; Turner *et al.,* 1999; Wang, 2001; Tonyushkina y Nichol, 2009; Clarke y Foster, 2012).

There are many blood glucose meters or glucose analyzers that are widely used in hospitals, emergency rooms, outpatient medical care, and at home for self-monitoring. Blood glucose meters are designed to measure glucose in either whole blood (capillary or venous), serum, or plasma, providing a quick analysis of blood glucose levels. They are useful for clinicians for consultation or in field work as well as for patients with diabetes, allowing them to test themselves and help better manage their blood glucose (Tonyushkina y Nichol, 2009; Clarke y Foster, 2012).

The HemoCue (HC) is a portable, fast, simple and reliable system for the determination of total blood glucose by the glucose dehydrogenase modified method. It uses integrated quality control and is very safe, requires little volume of whole blood, and is an instrument accepted by the Clinical Laboratory of Thomas Jefferson University Hospital (Torjman *et al.,* 2001*)*. Beyond obtaining the results in a very short time (from 40 to 240 " depending on the glucose concentration in the sample), the results are also comparable to glucose con-

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centrations obtained using traditional laboratory methods. Capillary or venous blood, as well as whole arterial blood, can be used for glucose analysis by the HC method, making it possible to use in laboratory or field work (Meyer *et al.,* 1998; 2001; Marley *et al.,* 2007; Tonyushkina y Nichol, 2009; Torjman *et al.,* Reddy *et al.,* 2014).

In fieldwork, especially in remote areas, it is difficult to immediately analyze the blood samples obtained, since often there are not adequate facilities or appropriate tools to do so in the visited communities. Tools such as the HemoCue (HC), which measures glucose concentration shortly after the sample has been obtained, can be very useful. The objective of this work was to compare the HemoCue technique against the GOx method for blood glucose measurement using data from a cross sectional study of diabetes in Comcáac (Seri) adults of Punta Chueca and El Desemboque, Sonora.

MATERIALS AND METHODS

All Comcáac residents of Punta Chueca and El Desemboque, Sonora who were 20 years of age or older were invited to participate in a cross sectional survey through a face-to-face home interview conducted by trained personnel and the health promoter of each community. Informed consent was obtained from subjects before participation in the protocol approved by the ethics committee of the Centro de Investigacion en Alimentacion y Desarrollo, A.C. in Hermosillo, Sonora, Mexico (number CE/005/2013). More details regarding the protocol can be found elsewhere (Robles-Ordaz *et al.,* 2018).

Approximately 7 mL of blood were taken from each participant, which was placed in a gray cap tube (with potassium oxalate and sodium fluoride as anticoagulant from the BD Vacutainer ™ system, Code 367925). To avoid glycolysis, once the blood samples were obtained they were kept on ice, until centrifugation at 3400 rpm for 15 min (Thermo Scientific Centrifuge, Sorval ST 40R, Germany) to obtain the plasma. The resulting plasma was poured in vials for storage in freezing (-20 °C) until transported to the city of Hermosillo to be stored at -70 °C at the biochemical laboratory of the Diabetes Research Unit of the Centro de Investigacion en Alimentacion y Desarrollo, A.C., where analysis was carried out as recommended (Sacks *et al.,* 2011; Urquidez-Romero *et al.,* 2014; ADA, 2015).

During field work, previous to sample centrifugation and after gently homogenizing each blood sample with anticoagulant, a drop of whole blood was taken for glucose analysis by the HemoCue β-glucose system (Hemocue Glucose 201+) (field method) (Sacks *et al.,* 2011; Urquidez-Romero *et al.,* 2014).

An oral glucose tolerance test was performed after a 10 – 12 h fasting period, using a 75 g glucose load (Dextrosol, catalogue number 5375; Hycel) according to the World Health Organization recommendations. Plasma glucose levels was determined before and after the 2-h post load condition by the GOx method (Randox GOD/PAP®) (traditional method).

The HC has internal quality control: its analyzer automatically checks the performance of its optical drive. In addition, it has two external controls of the HC System, low level and high level, with mean values manufacturer-labeled as 4.662 mmol / L (3.6075 – 5.7165 mmol / L), and 18.5925 mmol / L (16.0395 – 21.1455 mmol / L), respectively, which were evaluated during the field work at least once daily. In addition, the HC reading microcuvettes were handled and stored according to the recommendations of the manufacturing company (Eurotrol Glocotrol®-AQ (Ref 180.013.002, Eurotrol B.V., Keperlaan 20, 6716 BS Ede, The Netherlands). In the present study, a single measurement per collected sample was performed, with repeated measurements done only to corroborate in cases where there was doubt about the result obtained by HemoCue.

Plasma glucose (GOx technique) was determined by duplicate at CIAD laboratory. Using a colorimetric method based in a GOx reaction (GOD/PAP Randox®), serum controls were run (serum control level 2, catalog number: CAL2350A and serum control level 3, catalog number: HE2613, Randox) to assure quality control. All samples were read in a semi-automatic clinical chemistry analyzer RX Monza.

A total of 736 of blood glucose measurements were obtained from this study. 368 were obtained using the HC technique (field method) and 368 using the GOx (traditional method). Data were divided into five groups: group 1, all glucose measurements no matter the glucose level; group 2, glucose measurements less than 5.55 mmol / L; group 3, glucose measurements less than 6.993 mmol / L; group 4, glucose measurements greater than or equal to 5.55 mmol / L; and group 5, glucose measurements greater than or equal to 6.993 mmol / L.

Statistical analysis

Results were compared using Bland and Altman plots. The mean difference between HC and GOx measurements was considered as the dependent variable and the average of the measurements as the independent variable. The magnitude of overestimation was evaluated when the mean value of the differences between the method (bias or measurement error) was above the zero line (zero line considered as the perfect agreement between methods); or underestimate, when the mean value of differences was below the zero line. In each case, over or underestimation of HC methods were considered significant regarding GOx when the p-value obtained by the paired t-test comparing the mean value of the differences between methods was less than or equal to 0.05 (comparing differences in mean glucose of the HC against the GOx method). If the p-value of this test was higher than 0.05, there was no significant difference between the two methods, i.e., the means of the differences were equal to zero. The concordance limits were also estimated in the Bland and Altman plots as reported (Bland y Altman, 1986).

Simple linear regression was used to assess whether differences in glucose values between the two methods exhibited a lack of homogeneity of differences across the averages between methods. Whether differences in glucose

values exhibited trends of under or overestimation of the HC method was determined based on the beta parameter (negative or positive value, respectively) and its corresponding p-value. A trend of under or overestimation was considered when beta was negative or positive with corresponding p-value ≤ 0.05. Otherwise, when the p value was > 0.05, the differences were considered to be homogeneous along the average values of the glucose concentrations measured by the two methods.

The percentage of errors or residuals falling outside the Bland and Altman concordance interval was also estimated by counting the individual values and their percentage expression in relation to the total population analyzed per group. All analysis was performed using STATA version 14.1 statistical software program (Stata Corp LP, College Station, Texas, U.S.A.).

RESULTS

Means (± SD) of the glucose measurements by the HC and GOx methods of all groups defined by glucose levels are shown in Table 1. In Group 1, the mean of glucose measured by the HC was 6.639 ± 2.283 mmol / L and 6.637 ± 2.387 mmol / L by the GOx. In Group 2, the mean of glucose measured by the HC was 4.86 ± 0.471 mmol / L and 4.866 ± 0.432 mmol / L by the GOx. Similarly, in Group 3, the mean of glucose measured by the HC was 5.486 ± 0.699 mmol / L and that of GOx was 5.443 ± 0.688 mmol / L. In Group 4, the mean of glucose measured by the HC was 7.897 ± 2.459 mmol / L and that by GOx was 7.952 ± 2.586 mmol / L. In Group 5, the mean of glucose measured by HC was 10.021 ± 2.592 mmol / L and 10.193 ± 2.723 mmol / L by the GOx.

The concordance or agreement between the HC and GOx methods for each studied group was evaluated by Bland and Altman plots, paired t-tests, and linear regression analyses. In this graph, the concordance of the method of interest (in our case, the HC) against the method used as a reference (the GOx) was evalauted by comparing the average of the mean difference line, against the zero line (average differences equal to zero). The zero line is defined in the graph as the line of perfect agreement, considering a complete concordance or agreement when both lines are transposed (Rebel *et al.,* 2012).

Figure 1 shows the Bland and Altman plot of the difference in glucose measurements between the compared methods against its averages for Group 1. The mean of glucose differences between methods was 0.02 mmol / L, which was not significantly different from zero (p = 0.9555). This result indicates a concordance between the methods when all glucose measurements are included in the analysis (Group 1). However, the regression line indicates (β = - 0.0045, p = 0.0046) that the mean of glucose differences between methods (y line) did not have a homogeneous or consistent distribution over the range of glucose averages; in other words, as the average of glucose between methods increases (x line), the glucose levels measured by the HC were lower than those measured by the GOx. The limits of agreement were - 1.398 (- 2SD) to 1.402 (2SD) with 5.71 % of differences or errors outside the limits of concordance.

Table 1. Mean glucose levels measured by the HemoCue and GOx methods organized by groups of glucose concentrations.
Tabla 1. Valores de media de los niveles de glucosa medidos por los métodos de HemoCue y glucosa oxidasa en grupos formados en base a la concentración de glucosa.

	HemoCue* (mmol / L)	Glucose oxidase* (mmol / L)
Group 1 *(n=368)*	6.639 ± 2.283	6.637 ± 2.387
Group 2 *(n=95)*	4.86 ± 0.471	4.866 ± 0.432
Group 3 *(n=248)*	5.486 ± 0.699	5.443 ± 0.688
Group 4 *(n=197)*	7.897 ± 2.459	7.952 ± 2.586
Group 5 *(n=80)*	10.021 ± 2.592	10.193 ± 2.723

*Data presented as mean ± standard deviation. Group 1 (all glucose measurements); Group 2 (glucose measurements < 5.55 mmol / L); Group 3 (glucose measurements < 6.993 mmol / L); Group 4 (glucose measurements ≥ 5.55 mmol / L); Group 5 (glucose measurements ≥ 6.993 mmol / L)

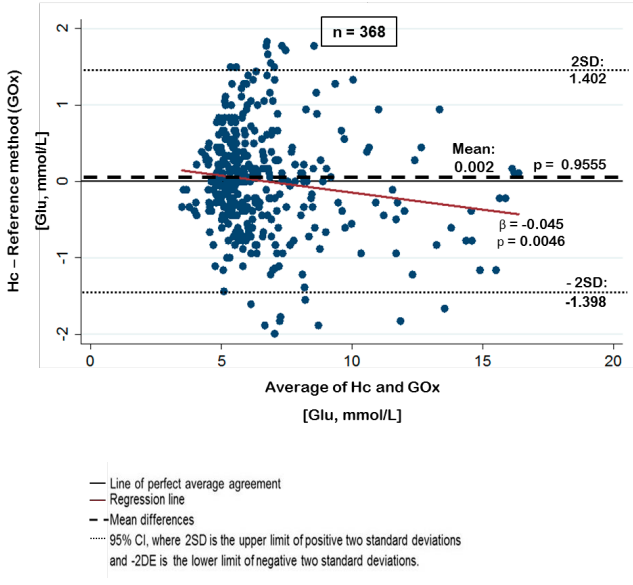

Figure 1. Mean difference for glucose measurements between HemoCue and Glucose oxidase method (reference method) versus their glucose average (mmol / L), for all glucose values.
Figura 1. Diferencia de media vs promedio de glucosa (mmol / L) para los valores de glucosa entre los métodos HemoCue y glucosa oxidasa (método de referencia) para todos los valores de glucosa juntos.

Figure 2 shows the Bland and Altman plot of the difference in glucose measurements between methods against its averages for Group 2. The mean of glucose differences between methods for this group was - 0.006 mmol / L; similar to that of Group 1, the mean in Group 2 was also very close to zero (p = 0.8684). Furthermore, the regression line indicated that mean differences had a homogeneous distribution (β = 0.1064, p = 0.2636) over the range of glucose averages used

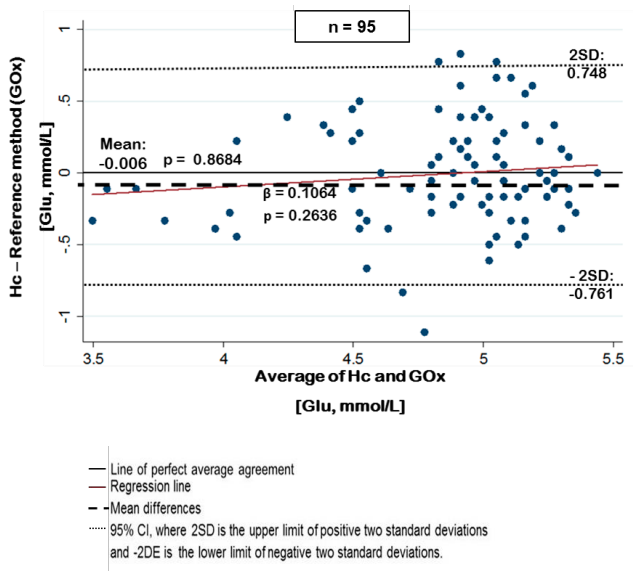

Figure 2. Mean difference for glucose measurements between HemoCue and Glucose oxidase method (reference method) versus their glucose average, for people with glucose values < 5.55 mmol / L.
Figura 2. Diferencia de media vs promedio de glucosa (mmol / L) entre los métodos HemoCue y glucosa oxidasa (método de referencia) para personas con valores de glucosa < 5.55 mmol / L.

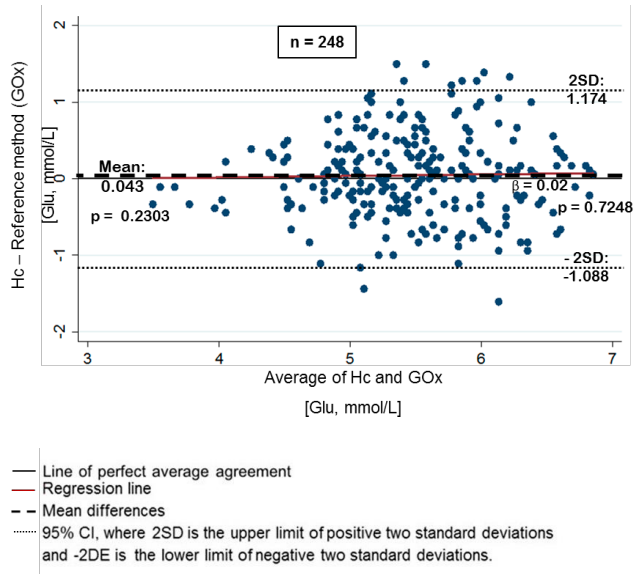

Figure 3. Mean difference for glucose measurements between HemoCue and Glucose oxidase method (reference method) versus their glucose average, for people with glucose values < 6.993 mmol / L.
Figura 3. Diferencia de media vs promedios de glucosa (mmol / L) entre los métodos Hemocue y glucosa oxidasa (método de referencia) para personas con niveles de glucosa < 6.993 mmol / L.

in Group 2 (glucose measurements < 5.55 mmol / L) or normal glucose level. The limits of agreement were - 0.761 (- 2SD) to 0.748 (2SD) with 5.26 % of differences or errors outside the limits of concordance.

For Group 3 (Figure 3) the Bland and Altman plot shows a good concordance between the compared methods, as the mean glucose difference was near zero (0.0432, p = 0.2303). Furthermore, the mean glucose differences were homogeneously distributed (β = 0.02, p = 0.7248) over the glucose concentrations that defined Group 3 (glucose levels lower than 6.993 mmol / L). The limits of agreement were - 1.088 (- 2SD) to 1.174 (2SD) with 5.24 % of differences or errors outside the limits of agreement.

Figure 4 shows the Bland and Altman plot of the difference in glucose measurements between the compared methods against its averages for Group 4. Similar to Group 1, a good concordance between the methods was shown as the mean glucose difference was near zero (- 0.056 mmol / L, p = 0.3128). The regression line indicated that the mean glucose differences between methods (y line) did not have a homogeneous or consistent distribution over the range of glucose averages used in group 4 (β = - 0.052, p = 0.0193); in other words, as the glucose average increases (x line), the glucose levels measured by the HC were lower than those measured by the GOx. The limits of agreement were - 1.599 (- 2SD) to 1.488 (2SD) with 7.61 % of differences or errors outside the limits of concordance.

Finally, for Group 5, a lack of concordance was found between the methods (Figure 5), since the mean of glucose differences was less than zero (- 0.173 mmol / L, p = 0.0350). In this case, the regression line showed that the mean differenc-

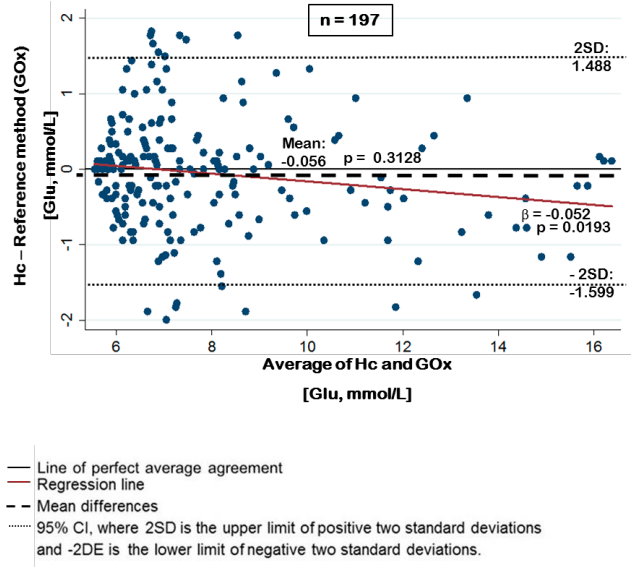

Figure 4. Mean difference for glucose measurements between HemoCue and Glucose oxidase method (reference method) versus their glucose average, for people with glucose values ≥ 5.55 mmol / L.
Figura 4. Diferencia de media vs promedio de glucosa (mmol / L) entre los métodos HemoCue y glucosa oxidasa (método de referencia) para personas con niveles de glucosa ≥ 5.55 mmol / L.

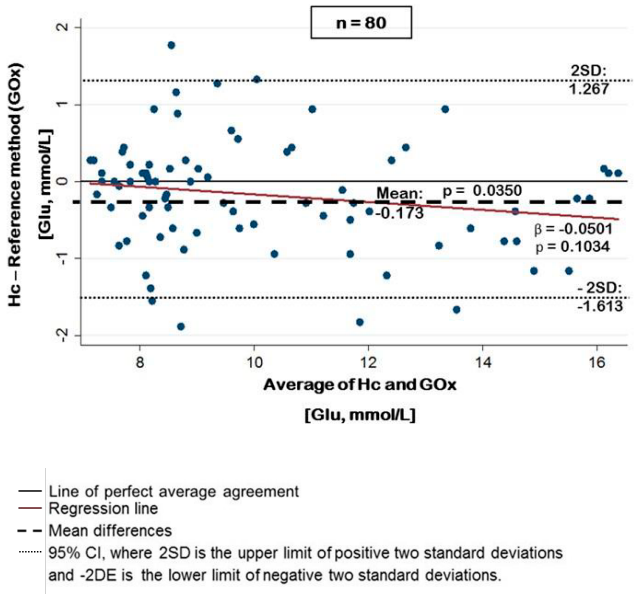

Figure 5. Mean difference for glucose measurements between HemoCue and Glucose oxidase method (reference method) versus their glucose average, for people with glucose values ≥ 6.993 mmol / L.
Figura 5. Diferencia de media vs promedio de glucosa (mmol / L) entre los métodos HemoCue y glucosa oxidasa (método de referencia) para personas con niveles de glucosa ≥ 6.993 mmol / L.

es were homogeneously distributed (β = - 0.05, p = 0.1034) in the range of high glucose levels (≥ 6.993 mmol / L). In other words, the glucose levels measured by the HC were lower than those measured by the GOx at for all values included in Group 5. The limits of agreement were - 1.613 (- 2SD) to 1.267 (2SD) and that 7.5% of differences or errors were outside the limits of concordance.

It is important to take into account that in the present study, glucose measurements were performed on different specimens (venous total blood and plasma) and also relied on different mechanisms. For instance, the GOx method is based on the enzymatic oxidation of glucose in the presence of the enzyme glucose oxidase and the HC is based in a modified technique of glucose dehydrogenase using the saponification of erythrocytes.

Several studies have made comparisons of blood glucose levels measured with different glucometers in different types of glucose samples and with different types of methods. Some of these studies were focused on the clinic practice, while others focused on hospitalized patients, newborns, or diabetic patients self-monitoring their glucose. However, few studies have been focused on the HC as a method to measure glucose in the fieldwork as part of a research study (Dohnal *et al.,* 2010; Ignell y Berntorp, 2011; Warner *et al.,* 2011; Pfützner *et al.,* 2012; Salacinski *et al.,* 2014; Sudha *et al.,* 2014;).

Sudha and collaborators in 2014 compared the HC 201 system, the B Braun glucometer, and the GOx technique used in a reference clinical laboratory. Patients were neonates from the Neonatal Intensive Care Unit. Glucose was measured in capillary and venous whole blood with the two glucometers and in plasma samples using the GOx technique in the reference clinical laboratory. The result showed that glucose levels measured by the B Braun glucometer were significantly higher than those measured in plasma by the GOx technique (5.561 ± 2.686 mmol / L vs 4.271 ± 2.552 mmol / L, p = 0.003) and those measured by HC (5.561 ± 2.686 mmol / L vs 4.60 ± 2.853 mmol / L). On the contrary, a non-significant difference was found between the glucose measured by the HC and that obtained by the GOx method (4.60 ± 2.853 mmol / L vs vs 4.271 ± 2.552 mmol / L), even in the lowest glucose range (< 3.0525 mmol / L) (p = 0.463). The authors concluded that the HC was a device suitable for glucose analysis in the neonatal care unit, since the results obtained showed an excellent correlation with those obtained by the GOx in the laboratory (Sudha *et al.,* 2014).

Similarly, in the present study, a non-significant difference was found when comparing the glucose measured by the HC and the GOx methods when all glucose values were analyzed as well as when glucose measurements were lower than 6.993 mmol / L (Figure 1 to 4).

In a study carried out in 2005 by Stork *et al.,* in hospitalized diabetic patients, glucose values analyzed by HC and the Yellow Springs Instrument glucose analyzer (YSI), which uses the GOx technique, where compared. Glucose values measured with the HC system was highly correlated with those measured by the YSI analyzer in a wide range of glucose concentrations, which led the authors to conclude that both methods can be used interchangeably for clinical and research purposes in the studied adult population.

Our results resemble those found by Stork *et al.,* in 2005. As in our work, they found a close relationship between HC and the reference method used in normal glucose concentration ranges. However, they also noticed that HC overestimates glucose values at concentrations greater than 11.0445 mmol / L, while in the present study it was found that at glucose values above 6.993 mmol / L, HC underestimated the glucose concentration.

When analyzing the differences between the group methods, it was observed that most of the differences (errors or biases) were within ± 2SD (Group 1 = 94.74 %, Group 2 = 92.4 %, Group 3 = 94.8 %, Group 4 = 94.8 % and Group 5 = 94.3 %). Stork and collaborators and Torjman and collaborators showed that 97 % and 95 % of their differences were within the limits of agreement (± 2SD), which was very similar to what was found in our study (Torjman *et al.,* 2001; Stork *et al.,* 2005).

Several studies have measured the accuracy of HC when compared to other routinely used methods in laboratories and to different types of glucometers with contradictory findings. While some conclude that the HC is an effective device for measuring blood glucose (Bellini *et al.,* 2007; Leonard *et al.,* 1997), some conclude that HC overestimates glucose levels (Stork *et al.,* 2005), and others conclude that HC underestimates glucose levels (Torjman *et al.,* 2001). In the opinion of some of these authors, the results could be influenced by external factors that played an important role in these variations and even by the concentrations of glucose

(Torjman *et al.,* 2001; Stork *et al.,* 2005; Leonard *et al.,* 1997). In the present work, and with the understanding that there were no duplicates of the measurements made in HC, special care was taken in the handling of the samples, both in the HC equipment as well as with its microcuvettes, in order to minimize the influence of external factors. With the GOx technique duplicate samples were taken, and the coefficient of variation (CV) for total plasma glucose values was 1.19 %, < 5.55 mmol / L values CV: 1.12 %; > 5.55 mmol / L values CV: 1.24 %; < 6.993 mmol / L values CV: 1.17 % and > 6.993 mmol / L values CV: 1.25 %.

For studies measuring blood glucose it is important to consider the accuracy and variability of the reference method used, since the gold standard, isotopic dilution mass spectrometry, is very expensive and therefore difficult to access in any laboratory. Therefore, a discrepancy between two paired measurements of two different devices or techniques does not necessarily imply that the tested method is not as accurate as the reference method used; rather, more research is needed on the performance validation of these portable instruments, especially if values are used interchangeably between whole blood and plasma (Rebel *et al.,* 2012).

CONCLUSIONS

These results showed concordance between the HC and GOx methods, mainly at glucose levels less than 6.993 mmol / L. The HC glucose analyzer was good for use in research studies since it is technically easy and requires very little maintenance; however, it is recommended that special care be taken with those people with borderline glucose values, or those within the limits of diabetes diagnosis, since there is a risk of misclassifying persons that already have diabetes as not having diabetes when using the HC method. Thus, given the importance of knowing the real values of glucose levels in this group of people for an accurate diagnosis, it is recommended to consider a subsequent analysis with the GOx method to corroborate the result.

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