LABORATORY MEDICINE

Comparison of Outpatient Point of Care Glucose Testing vs Venous Glucose in the Clinical Laboratory

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The purpose of this study was to evaluate the accuracy of glucometers in assessing glucose levels in outpatients. The investigation consisted in the analysis of retrospective validation data (obtained at the Clinical Laboratory of the Puerto Rico Medical Services Administration) and the analysis of data obtained from forty outpatients. Glucose concentration was obtained from these outpatient samples using the patients' glucometers and a clinical laboratory analyzer (hexokinase method). Statistical analysis included descriptive and correlation measures and t-test. Results revealed that accurate glucose values were obtained by the glucometers utilized in both the validation process and the outpatients (POCT) procedure. The investigation also demonstrated the need by outpatients to receive proper training in handling their glucometers.

Key words: POCT, Glucometers, Outpatients, Home setting

The evolution of Point-of-Care Testing (POCT) technology since the 1980s is changing laboratory operations. POCT is any laboratory testing, at any complexity level, performed and documented within the hospital at sites that are located outside the central laboratory (1). POCT is also called near-patient testing, ancillary testing, decentralized testing, and bedside testing (2). The testing technology to support POCT is in the form of transportable and hand-held units. It should be precise and accurate and should require minimal training and troubleshooting (3).

Among the variety of analytes reported in the literature for POCT, glucose is one of the most measured. Ancillary blood glucose testing (ABGT), as performed by trained personnel, provides rapid and sufficiently reliable blood glucose testing results that are used by the medical staff to make therapeutic decisions (4). The success of the program is based on adequate training of the personnel and in good equipment maintenance.

As bedside glucose testing by nonlaboratory personnel proliferated, concerns were raised about accuracy, quality control and documentation of the results (5). The conclusions of the studies done by the College of American Pathologists indicate the need of improving bedside glucose monitoring (BGM) accuracy performance (6,7). A study done by Goff and Rogers in outpatient clinics revealed variability in the accuracy of the monitors tested, especially in the higher ranges, which could result in undertreatment of hyperglicemia (8).

The National Committee for Clinical Laboratory Standards (NCCLS) establishes that for ABGT test readings greater than 100 mg/dL, the discrepancy between ABGT concentrations and laboratory concentrations on the same specimen should be less than 20% and for ABGT test readings of 100 mg/dl or less, the discrepancy should be no more than 15 mg/dL (4).

Previous work has focused on settings in which trained personnel is in charge of sample testing and monitoring. This study is focused in the use of POCT by patients in the home setting.. The use of glucometers by outpatients has proliferated during recents years. Concern about the concordance of these results with those obtained in the laboratory with venous blood was the reason of this study.

Our objectives were to: 1) compile data of glucose levels obtained by diabetic outpatients who use a POCT analyzer by the clinical laboratory and compare the results for acccuracy, 2) analyze retrospective data of the validation process from the POCT program of the Clinical Laboratory of the Puerto Rico Medical Services Administration (ASEM) and to 3) compare the accuracy of the values obtained by outpatients with that obtained by the validation process. We present data supporting that the POCT technology yields acceptable results for monitoring

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the glucose levels of diabetic patients. Nevertheless, we emphasize that the handling of the instruments need to be improved.

Methods

An advertisement was posted recruiting diabetic patients over 21 years old who owned and used a glucometer for monitoring their glucose levels. These patients were from the towns of Camuy and Hatillo, in the nortern coast of the Island, as well as Caguas (Central Region) and Río Piedras, in the greater San Juan Area of Puerto Rico.

These patients took a fasting fingerstick sample and processed it in their own glucometers. Among these glucometers were: Prestige LX (Home Diagnostics, FL); One Touch Basic (Johnson & Johnson, CA); One Touch II (Johnson & Johnson, CA); One Touch Profile (Johnson & Johnson, CA); Select GT (Chronimed, MN); Precision QID (MediSense, MASS); Accu-Chek Advantage (Roche Diagnostics, IN); Accu-Check Instant (Roche Diagnostics, IN); SureStep (Johnson & Johnson, CA); Glucometer Elite (Bayer,NY) and Assure (Chronimed, MN). Direct observation of how these patients handle their instrument was done.

A venous glucose sample was obtained from these patients within five minutes after the fingerstick sample. These samples were analyzed in the instrument RA 500 (Bayer Corporation, NY) by the hexokinase method. The procedures followed were in accordance with the ethical standards of the Institutional Review Board (IRB code: 5020101).

The validation of bedside glucose monitoring in the Clinical Laboratory of the Puerto Rico Medical Services Administration was based in the duplicate analysis of forty patient glucose samples by each of eleven Glucometer Encore blood glucose meters (Bayer Corporation, NY) and by a reference method, glucose hexokinase, using the DAX analyzer (Bayer Corporation, NY). We used only the validation data of one of these glucometers. Comparison studies were done for evaluating the two methods. The significance of the difference in results between the two methods was evaluated by plotting a comparison graph, determining the slope and Y intercept, utilizing the paired t test, calculating the correlation coefficient and determining the standard error of the estimate.

Sample collection. The assay by the glucometers required 8-20 ul of whole blood by fingerstick. Non hemolyzed fasting blood was collected by standard venipuncture technique for the assay in the DAX instrument. The samples were processed within 8 hours. For the RA-500, fasting plasma was taken in sodium fluoride as preservative. The samples were processed within 2 hours.

Hexokinase method principle. The glucometer Encore whole blood glucose test is based on the hexokinase method using dry reagent technology. Glucose in the serum or plasma portion of the blood reacts with components in the reagent area of the test strip to produce color. In the reaction process the reagent containing hexokinase, ATP and magnesium reacts with glucose to produce glucose – 6-phosphate. The glucose-6-phosphate reacts with glucose-6-phosphate dehydrogenase and nicotinamide adenine dinucleotide to produce nicotinamide adenine dinucleotide phosphate. The nicotinamide adenine dinucleotide phosphate (NADPH) then reacts with diaphorase and the tetrazolium indicator to produce a brown compound (formazan) with the intensity of the brown color directly proportional to the plasma glucose concentration in the whole blood sample.

The strip is introduced in the glucometer, which measures the reflected light in electronic form and the results are visualized in the digital screen. The test provides a quantitative measurement of glucose in whole blood from 10 to 600 mg/dl. The manufacturer instructions were followed using the glucometer Encore System Kit (9).

The principle of hexokinase method is the same for both instruments DAX and RA-500. Phosphorylation of glucose by ATP occur and the end product of the reaction, NADPH, is measured photometrically by the increase in absorbance. The amount of NADPH formed is equivalent to the amount of D-glucose in the specimen (10,11).

Statistical analysis. For the validation process , comparison of quantitative variables by procedure was performed, using Microsoft® Excel 97 version. Regression, slope, intercept and t tests were calculated. For the outpatients (POCT) , statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 9.0 (12). The two procedures were evaluated for acceptable performance using correlation and regression statistics.

Results

In table 1 the values of the correlation coefficient, standard error, intercept, slope and t-test for the forty samples of the validation process and for the other forty outpatients were compared. In the validation process between reference method and glucometer, intercept was 1.34 with a slope value of 0.96. The statistics of the process of POCT by outpatients reflected a higher systematic error, with values for the intercept and slope of 13.39 and 0.77 respectively.

Table 1. Correlation data

	Validation	Outpatients
	ASEM	POCT
Correlation coefficient	0.99	0.93
Standard error	7.03	19.14
Intercept	1.34	13.29
Slope	0.96	0.77
T-test	0.8	0.05
Observation (n)	40	40

The difference between both process is due to the glucometers diversity used by outpatients; meanwhile only one glucometer was used for the validation process. The t-test value of 0.8 for the validation and 0.05 for outpatients (POCT) are not significant for an alpha= 0.05 and alpha=0.01 as shown in table 2.

Table 2. Critical t values

Significance level	
5% (0.05)	2.02
1% (0.01)	2.71

In table 3 the forty patients of the hospital had comparable and acceptable results as established by the National Committee for Laboratory Standards. In table 4, nine results of the forty outpatients samples fall out of the acceptable range of 22.5 %. All nine outpatient samples were over the glucose level of 100 mg/dl.

In the validation process all the factors of calibration, quality control and maintenance of the glucometer were controlled. Regarding these previously mentioned factors only six of the forty outpatients correctly handled their glucometers. Seven of the nine outpatients with glucose results out of range did not handle their glucometers properly. Figures 1 and 2 shown that both the validation process and the POCT for outpatients present a linear correlation between the laboratory results and the glucometers results.

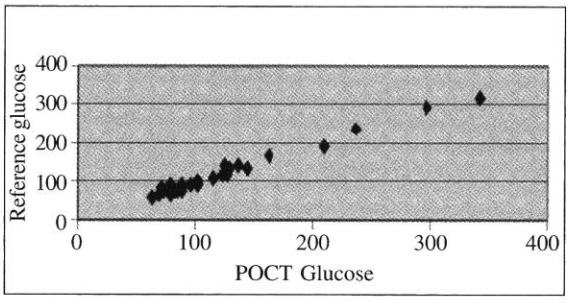

Figure 1. Validation data POCT = Point of care testing Internal scale = concentration of glucose in milligrams per deciliters

Table 3. Validation data

No. subject	Lab results	Glucometers results	Acceptable range
1	64	61	49 - 79
2	70	69	55 - 85
3	71	81	56 - 86
4	73	73	58 - 88
5	77	79	62 - 92
6	77	76	62 - 92
7	79	83	64 - 94
8	79	66	64 - 94
9	79	89	64 - 94
10	80	77	65 - 95
11	81	82	66 - 96
12	81	81	66 - 96
13	81	78	66 - 96
14	81	76	66 - 96
15	82	76	67 - 97
16	84	74	69 - 99
17	85	77	70 100
18	86	84	71 - 101
19	88	90	73 - 103
20	88	87	73 - 103
21	88	83	73 - 103
22	88	77	73 - 103
23	89	93	74 - 104
24	96	91	81 - 111
25	101	94	80.8 - 121.2
26	101	93	80.8 - 121.2
27	102	100	81.6 - 122.4
28	103	94	82.4 - 123.6
29	116	107	92.8 - 139.2
30	123	115	98.4 - 147.6
31	126	139	100.8 - 151.2
32	127	115	101.6 - 152.4
33	130	131	104 - 156
34	137	138	109.6 - 164.4
35	145	133	116 - 174
36	162	166	129.6 - 194.4
37	210	189	168 - 252
38	237	237	189.6 - 284.4
39	297	297	237.6 - 356.4
40	343	321	274.4 - 411.6

Table 4. Outpatients (POCT) data

No. subject	Lab results	Glucometers results	Acceptable range
1	121	*81	96.8 - 145.2
2	169	*107	135.2 -202.8
3	169	*99	135.2 - 202.8
4	175	*121	140 -210
5	180	195	144 - 216
6	232	*142	185.6 - 278.4
7	84	88	69 - 99
8	94	96	79 - 109
9	95	85	80 - 110
10	104	95	83.2 - 124.8
11	106	87	84.8 - 127.2
12	113	103	90.4 - 135.6
13	117	115	93.6 - 140.4
14	126	114	100.8 - 151.2
15	127	112	101.6 - 152.4
16	127	110	101.6 - 152.4
17	131	115	104.8 - 157.2
18	131	*102	104.8 - 157.2
19	133	140	106.4 - 159.6
20	135	129	108 - 162
21	137	*108	109.6 - 164.4
22	143	131	114.4 - 171.6
23	155	150	124 - 186
24	156	146	124.8 - 187.2
25	166	135	132.8 - 199.2
26	168	148	134.4 - 201.6
27	170	147	136 - 204
28	174	153	139.2 - 208.8
29	175	145	140 - 210
30	190	*143	152 - 228
31	198	196	158.4 - 237.6
32	203	182	162.4 - 243.6
33	211	187	168.8 - 253.2
34	223	184	178.4 - 267.6
35	227	207	181.6 - 272.4
36	237	213	189.6 - 284.4
37	263	239	210.4 - 315.6
38	263	*205	210.4 - 315.6
39	298	252	238.4 - 357.6
40	360	288	288 - 432

*Not acceptable

Discussion

The graphics indicate that a linear correlation exist between the pair of results of both procedures. There is no significant difference between the results obtained by the hexokinase method and the dry technology used by the glucometers. Seventy eight percent of the outpatients had comparable and acceptable results using their glucometers. Although eighty five percent of the outpatients do not handle properly their instruments our results validate the use of glucometers in POCT manner.

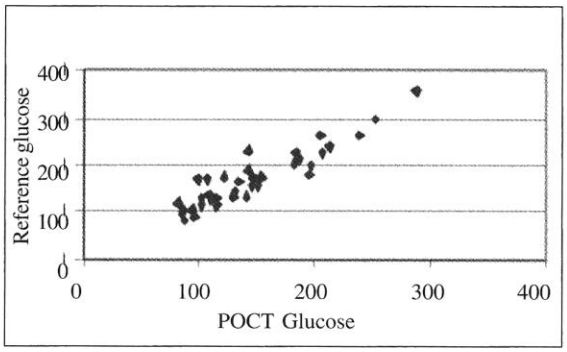

Figure 2. Outpatients POCT data/POCT = Point of care testing/Internal scale = concentration of glucose in milligeams per deciliters

Additional support for glucometers accuracy was found in the validation of the hospital. One hundred percent of the validation results were within the acceptable range. The statistics values obtained for the validation process reflected more accuracy and precision due to a controlled environment that those obtained by the outpatients.

Although this study seems to suggest that POCT glucometers are accurate we are aware that the sample population was very small. Therefore we recommend an expansion of this pilot study to include more outpatients. Future studies can help determine until which glucose concentration the values obtained by the glucometers are reliable. In order to reduce the erroneous results obtained in the glucometers by the outpatients, continous orientation must be offered to diabetic patients who use these instruments and their family members. The medical community have to make them aware of the clinical importance of using their glucometers adequately.

Acknowledgements

The authors gratefully acknowledge the support of Dr. Margarita Irizarry, Clinical Laboratory Science Research Coordinator and Dr. Luis Ramos, the Borinquen Clinical Laboratories Medical Consultant, for his critical review. We specially want to thank Dr. Robert Whitlock*, Borinquen Clinical Laboratories Director, for the use of their facilities, materials, an reagents and the help in data collection. We also wish to thank López Clinical Laboratory, of the Monte Mall Clinical Laboratory, the

Rodríguez Clinical Laboratory and the Clinical Laboratory of Puerto Rico Medical Services Administration for their help in data collection.

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