Accuracy evaluation of point-of-care glucose analyzers in the Saudi market

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Blood glucose meters are widely used in point-of-care testing (POCT). Diabetic patients also use them as a major tool for managing their disease. Clinicians are continuously demanding improved accuracy for bedside glucose monitors as they adopt protocols for better glycemic management of their patients. Clinicians are also demanding that they would like to see the accuracy that is similar to lab instruments in the point-of-care glucose systems. Many western studies have compared the blood glucose meters available in their markets, and have shown their sensitivities and accuracies and proposed their recommendations based on these results.[1-3] Very few such studies are available in the Middle Eastern literature. One such epidemiological survey conducted at King Saud University, Abha, Saudi Arabia concluded that with the proper training of the user, the glucometer II is a practical and accurate instrument.[4] The purpose of this study was to evaluate the clinical performance of various bedside glucometers available in the local Saudi market.

The study was performed at the International Medical Center (IMC), and was conducted by the Department of Pathology and Laboratory Medicine, Point-of-Care Section. Five such glucometers, which are widely available in the Saudi market were selected for this comparative study: 1) Nova StatStrip, (Nova Biomedical, Waltham, MA, USA). 2) EasyMax Mettler-Toledo, (Autochem Inc., Columbia, MD, USA). 3) Omron (HEA-STP) (Arkray Factory Ltd, Dock Lane, Melton, Woodbridge, Suffolk, UK). 4) OneTouch (LifeScan Ltd., Burnaby, British Columbia, Canada. 5) Finetest™ (Infopia Co. Ltd., Anyang, Korea). All these devices and strips were handled and stored as per manufactures recommendation to maximize the accuracy of the results. Accuracy was determined for each meter by comparing the results with those of a laboratory glucose hexokinase method (Roche Diagnostics, GmbH, Mannheim, Germany), the accuracy of which was known from performance in external quality control schemes. A total of 40 samples were collected randomly from outpatient services that were requested for blood glucose test by the physician. This study was carried over a period of 20 days during June 2011. Both genders were included in the study (male n=20, and female n= 20), ages ranged from 25-67 years, with a mean age of 47 years. The sample collection criterion included: 1: Samples were collected from outpatient clinics regardless of gender, age, or clinical diagnosis. 2. Verbal consent from the patient was required, and the procedure was explained by the phlebotomist that an extra tube (heparin tube) will be drawn for this research. Institutional ethics committee approval was received to conduct this study. 3. Patient confidentiality was maintained, and only the tracking number of the specimen was used for analysis. 4. The testing protocols recommended by the manufacturer were followed. Both serum and heparinized whole blood samples were collected in 2 separate tubes. The serum sample was centrifuged and separated within 15 minutes and submitted for testing on the Roche laboratory analyzer (COBAS 501). Heparinized whole blood samples were submitted for testing on POC test strips. Sample analysis and testing were complete within a maximum of 45 minutes from initial blood draw. These heparinized samples were mixed properly before applying blood to the POCT device. Each sample was consecutively processed on all the 5 POCT devices in one sitting, avoiding any delays within one hour. Results were recorded separately for each device. Analyzed samples showed values ranging from 70-330 mg/dl. All the data collected was charted on an excel sheet and linear regression analysis was performed to illustrate the linearity of the points and the regression values. To determine how well the regression line fits the data, we calculated r-squared (r^2).[2] The r^2 value, which is a measure of goodness-of-fit of linear regression was calculated for each device. The value r^2 is a fraction between 0.0 and 1.0, and has no units. An r^2 value of 0.0 means that knowing X does not help you predict Y. There is no linear relationship between X and Y, and the best-fit line is a horizontal line going through the mean of all Y values. When r^2 equals 1.0, all points lie exactly on a straight line with no scatter. Knowing X lets you predict Y perfectly. Through calculated r^2 data we observed the performance of devices against the reference method in the main laboratory.

Of all the 5 devices we tested, the Nova StatStrip device showed excellent performance that almost agreed and correlated perfectly with the lab results (r^2=0.99). The 2 other devices that showed acceptable accurate performance were the Omron-HEA221 (r^2=0.94), and the OneTouch LifeScan (r^2=0.95) (**Table 1**). The other 2 devices (EasyMax and Finetest) showed lower acceptable performance (r^2=0.90 and 0.84), as the correlation factor showed high deviation from the Lab reference method, especially at extremely high and low levels of glucose.

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Table 1 - Linear regression analysis with calculated r^2 values for the 5 glucometers tested.

Device name	Strips	Slope (m)*	r^2
NOVA	StatStrip	1.008	0.99
OMRON HEA221	HEA-STP20	0.932	0.943
LifeScan-OneTouch	OneTouch ultra	0.953	0.953
Easy Max	Easy Max Voice	0.863	0.908
Finetest	Fine Test	0.839	0.843

*Slope defines the steepness of the line

One limitation of this study was that we only analyzed the glucometers available at the IMC pharmacy. Many other glucometers by various other vendors also available in the Saudi market were not included in this study. The second limitation of the study was that we used whole blood rather than capillary blood for testing on the glucometers.

In conclusion, we recommend that all hospitals should evaluate the bedside glucometers available in their market and put forward their recommendation to the end-user accordingly.

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