

A Study of the Accuracy of the Precision Q.I.D.TM Glucometer

Pages with reference to book, From 114 To 116

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Abstract

The Precision Quantum-in-dium (Q.I.D.)TM Glucometer was used to determine the glucose concentrations of 38 human blood samples. The same samples were also run on the OPERA Chemistry Autoanalyzer 2010 system. More than 44% of the glucometer reports had a difference of greater than 15% from the respective autoanalyzer reports. The calibration of the glucometer could be the source of the error and an improvement is recommended (JPMA 48: 114, 1998).

Introduction

Diabetes Mellitus is a common disease in Pakistan^{1,2}. It manifests in two forms: Insulin Dependent Diabetes Mellitus (I.D.D.M.) and Non-Insulin Dependent Diabetes Mellitus (N.I.D.D.M.). Periodical blood glucose monitoring is mandatory for both I.D.D.M. and N.I.D.D.M. In severe I.D.D.M. cases, the insulin dose determination may require knowledge of the blood glucose concentration.

Glucometers were introduced in the market to help the Health Professionals and people with diabetes. Initially such instruments worked on reflectance photometry. Lately more advanced Sensor Type Glucometers have appeared on the scene. They use the change in the electromotive force (e.m.f.) generated by the movement of electrons between electrodes because of the glucose oxidase reaction³. These glucometers provide a rapid and relatively convenient way of determining the blood glucose level, though their accuracy has often been questioned.

Investigations were taken up at the Biochemistry Department, Shaikh Zayed Hospital, Lahore¹ to determine the accuracy of the Precision Q.I.D.TM glucometer.

Materials, Methods and Results

The sensor glucometer works on semi-automatic glucose analyzing system. It consists of thin film glucose sensors and a flow injection system with a computerized data processing unit. Glucose oxidase is immobilized into a network of epoxy on the electrode strip together with potassium ferricyanide.

This acts as an electron mediator for reducing the operation voltage of the sensor⁴.

The glucometer calibration system uses a Standard Calibration Electrode Strip. One end of this is inserted into the Test Port Terminal of the sensor. It is designed to conduct a certain number of electrons to the sensor. The data processing unit reads this signal current and expresses it as a standard glucose concentration of 298 mg/dl (16.54 mmol/l) on the screen display.

The Test Electrode consists of a disposable strip inserted at the same terminal. One drop of blood (5-50 μ l)⁵ is applied to the "Target Area" on the electrode. The glucose oxidase reaction generates electrons, which cause a flow of current. The sensor compares this current with that from the Calibration strip and the glucose concentration relative to the standard 298 mg/dl (16.54 mmol/l) is displayed within 20 seconds⁴. Thirty-eight subjects were chosen randomly from the Medicine ward (4), Surgical ward (4), Outpatients Department (13), Ear Nose and Throat Ward (2), Eye Ward (3), Urology Ward (2), Orthopedics Ward (3) and Biochemistry Laboratory (7) of the Shaikh Zayed Hospital, Lahore.

From each subject, 1.50 ml venous blood was drawn. The identity of each subject was recorded for future reference. Within 5 minutes⁵ of drawing the blood, the first drop of each sample was applied to the glucometer electrode strip. The remaining sample was placed in a collecting tube. The glucometer reading was recorded. The collecting tubes had been prepared containing 1 mg Sodium Fluoride (NaF) and 3mg Ethylene Diamine Tetra Acetate (EDTA-Sodium). The sample in each tube was centrifuged to separate the plasma from the blood cells.

The plasma was run on the "OPERA" Chemistry Autoanalyzer 2010 system. This system employs the Hexokinase reaction. The reported glucose concentration was recorded for the comparison with the glucometer reports.

It may be clarified here that quality-control standard solutions were run repeatedly on the Opera Autoanalyzer. The accurate results proved that the system was working efficiently and properly.

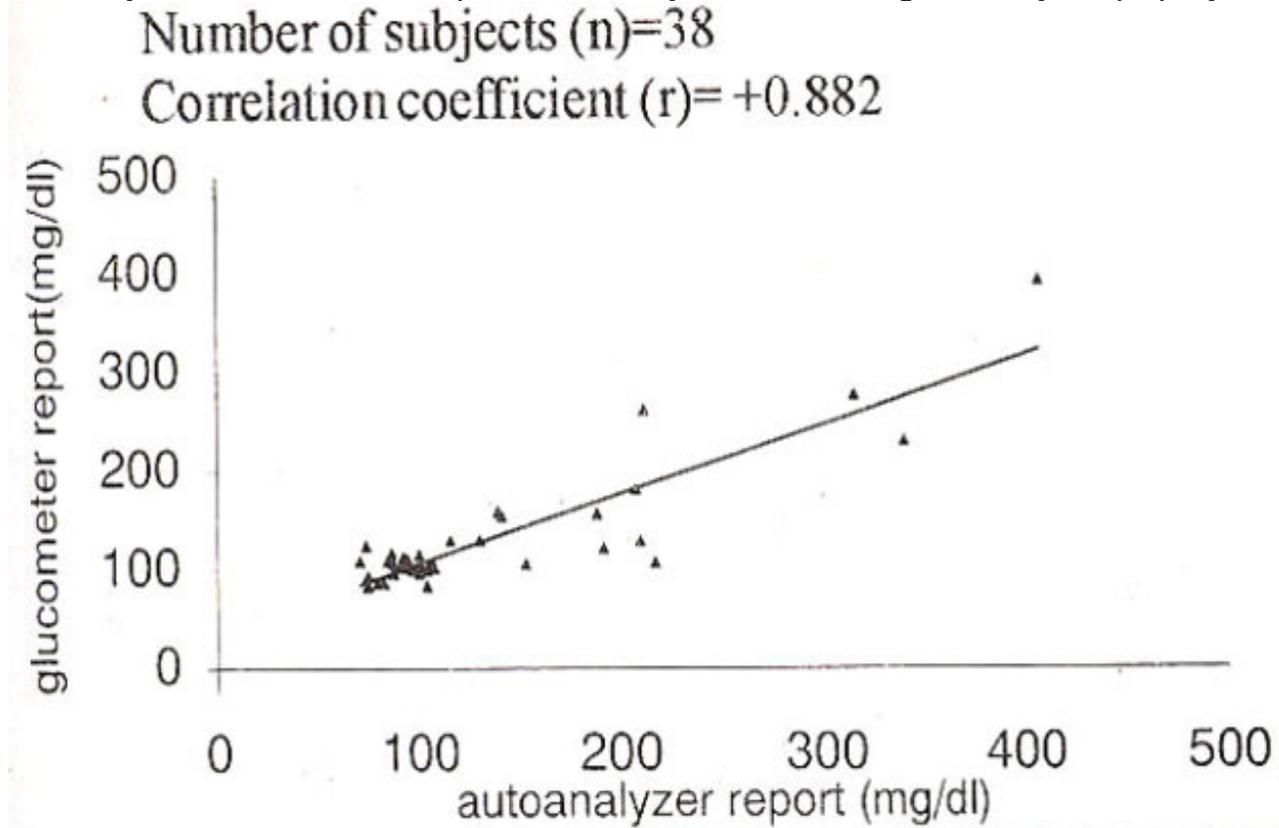


Figure 1. A comparison of the autoanalyzer and glucometer reports for the 38 blood samples.

Figure 1 shows the graphical comparison of the reports.

The regression analysis⁶ of the sample comparisons revealed: Slope (b)= 0.705 ± 0.0623 (1 SE) Y-intercept= +35.47 mg/dl (1.97 mmol/l) $S_{y.x}$ (S.E.E.) 29.31 mg/dl (1.63 mmol/l)

The r-value (as compared to the perfect 1.0) shows a relatively strong positive correlation between the glucometer and autoanalyzer results. However, the slope (see appendix-B) was significantly different from 1.0 ($t=4.74$, $p<0.0001$) which puts down the reliability of the glucometer³.

The number of glucometer readings: higher than autoanalyzer readings = 22 equal to autoanalyzer readings = 1 lower than autoanalyzer readings = 15

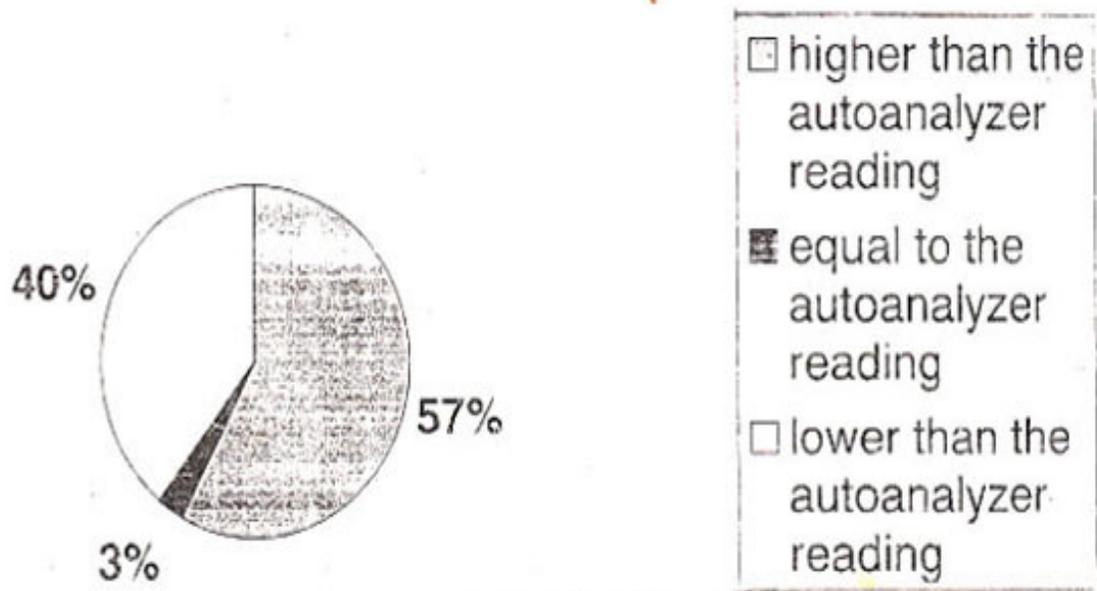


Figure 2. Percentage (n=38) representation of the glucometer results that differed from the autoanalyzer results.

Figure 2 shows the percentage pie chart of these results. More than forty-four percent (44%) of the glucometer results differ by >15% from the autoanalyzer results.

Discussion

The results show that the performance of the glucometer was not satisfactory. The large proportion of results showing a considerable difference (>15%) from the autoanalyzer is evidence that the device failed to meet the requirements of the American Diabetes Association standards³.

Although the device is relatively technique-independent, the possibility of faults in the operating technique may not be ruled out³.

The handling and storage of the equipment by the importers and distributors should also have followed the temperature range (4°C to 30°C) specified by the manufacturers⁵. This is essential for the ideal working of the enzyme system. If the strips were exposed to extreme temperatures, the enzymes of the system would have been altered explaining why about 40% of glucometer results were lower than the autoanalyzer results.

Improper calibration of the glucometer could create problems at two fronts:

The first is the built-in calibration by the manufacturer utilized to convert the results on the whole blood to equivalent values for serum. Any error in this regard would obviously create an error in the glucometer results. This would require stricter control on the part of the manufacturers^{3,4}.

The second fault could be the result of the Calibration Electrode (strip) system. If the strips were mishandled during storage or transport, the number of electrons (therefore the current) it conducts to the sensor would be altered. The sensor is designed to interpret whatever the magnitude of the current from the Electrode, as the standard 298 mg/dl (16.54 mmol/l) for this device. When the test strip is inserted and if it is giving a faulty current, the sensor would compare the "test" current from the (blood glucose) with the altered calibrator current and give a faulty reading.

This appears to be a logical explanation of the problem of inaccuracy and can be tested using electronic measurements. Better control on the calibration is recommended. If the Calibration Electrode is sending an altered current, the sensor should be able to detect these alterations. It should then adjust

the screen display, eliminating this error. This would require changes in structure and design of the sensor on part of the manufacturers. Changes should also be made in the Calibration Electrode to try to keep the current within narrow and detectable limits.

Acknowledgement

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