Upsala J Med Sci 91: 173–174, 1986

Determination of Blood Glucose by Reflectance Spectroscopy

Reliability when used in clinical routine

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Systems based on reflectance spectroscopy are nowadays frequently used for blood glucose determination, especially in outpatient care and at home monitoring of diabetic patients. This method is no doubt reliable when the analysis is performed by well-trained operators, and when the equipment is satisfactorily standardized, but the reliability is not known when the analysis is performed at less optimal conditions.

During the last four years we have on several occasions evaluated different reflometric systems, especially the Dextrostix-Glucometer system. The evaluations were based on determination of patient blood. From each patient two venous blood samples (EDTA- and heparin-fluoride blood) were drawn. The EDTA-blood was used for immediate reflometric determination and the heparin-fluoride blood was sent to our laboratory for determination of glucose by a wet chemistry method (glucose oxidase method adapted for the Greiner Selective Analyzer, GSA II). The standardization of the Glucometers were checked daily by the use of "chips" and recalibration against the chips was done only when the results were outside certain limits. Calibration with water standard was not used. The evaluations were performed during 2-3-month periods when the Glucometers were used in the clinical routine. In all, 30 operators with all possible degrees of experience used 8 different Glucometers, 15 different batches of the reagent strip and performed more than 900 determinations. The comparison method was carefully standardized and the total imprecision as judged from daily analysis of control samples was 4.3 per cent (CV) at the level of 5.6 mmol/L. The laboratory took part in the Wellcome Control Programme which showed that the mean results from the laboratory did not differ significantly from the mean of other laboratories using the same method.

When comparing the results obtained by the Dextrostix-Glucometer method and the wet chemistry method we observed that

- outliers, i.e. results diverging by more than 30 per cent, occurred in 2.4 per cent of all observations
- the most likely reason for these outliers was erroneous handling of the test strip or less likely, erroneous handling of the reading device (operator misstakes)

- during a 10-day period one operator was responsible for 8 outliers out of the total of 13 observations; later she obtained correct results
- when the analyses were performed by operators experienced in laboratory work no outliers were recorded
- after exclusion of outliers, 95 per cent of the results deviated by less than 20 per cent from the results of the comparison method
- some operators without laboratory experience constantly had a bad performance; otherwise no obvious correlations between skilfulness and degree of training was observed
- systematic deviations (less than $\pm$ 10 per cent) were observed from time to time which partly explained the low reliability
- these systematic deviations generally could not be attributed to the use of a special batch of the test strip
- when the analyses were performed by skilled operators significant differences related to the batch number of the test strip were observed, however.
- during 1985 most of the test strips used in our laboratory gave about one mmol/L too low results by about one mmol/L when calibration was performed against chips

In conclusion grossly incorrect results obtained by the Dextrostix-Glucometer system are generally related to the operator. The reading device, when properly handled, gives reproducible results. Systematic deviations, due to differences between batches of the test strip occur but due to the low precision of a single determination, the overall reliability is generally not improved by calibration with a water standard each time a new batch is to be used.