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Laboratory Assessment of Five Glucose Meters Designed for Self-Monitoring of Blood Glucose Concentration

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Summary: We describe a laboratory assessment of five blood glucose meters. The instruments' analytical characteristics under optimum laboratory conditions and examination of potential sources of errors were intercompared. All glucometers produced precise results, and in all but one meter the CV values varied between 1.5% and 6%. CV's for reproducibility and within-day precision of Glucometer Gx were 10.5% and 7.3%. Sample volume, blood incubation time and colour stability of the strip may influence the results of blood glucose measurements with glucose meters. Underloading the sample strip had statistically significant effects on normal blood glucose values for all meters. One Touch II gave also significantly different results when the strip was overloaded. Incubation times shorter or longer than those recommended by the manufacturer influenced the results of all glucose meters. After colour development of the strip, changes were small for Haemo-Glukotest 20-800R strips and Glucotrix, whereas Accutrend glucose strips had to be read immediately following the prescribed incubation time. Comparison of the glucose meter results with those obtained by the hexokinase method showed good correlation coefficients for Reflolux S ($r = 0.992$), Accutrend ($r = 0.988$), One Touch II ($r = 0.942$), Glucometer Gx ($r = 0.986$) and Glucocard ($r = 0.976$). Error grid analysis showed that the results of all meters were clinically correct. Variations in haematocrit are known to be a source of errors when blood glucose is determined with a test strip. In the normoglycaemic range the results obtained with Accutrend and Glucocard were not influenced by even extreme haematocrit values. In the high glucose concentration range there was a decrease in blood glucose values with increasing haematocrit for all meters. This error was smaller with Accutrend and Glucocard than with the other meters.

Although the new versions of the monitors are easier to use, their analytical performance is not superior to earlier models.

Introduction

Self-monitoring of blood glucose concentrations is a common practice in the routine management of diabetic patients (1).

Several devices are now available for monitoring glucose concentration in whole blood. Visually readable strips and reflectance photometers are widely used. While glucose determination by means of visual assessment of the test strips is limited to range-related comparison of developed colour, blood glucose meters are able to display continuous values. The reflectance photometers have undergone extensive modification in the past few years, and "improved versions" of

reflectance photometers of several manufacturers are on the market. We assessed the performance of five such instruments:

Reflolux S (Boehringer Mannheim Canada Ltd., Dorval, Quebec),

Accutrend (Boehringer Mannheim Canada Ltd, Dorval, Quebec),

One Touch II (Lifescan Inc., Mountain View, CA 94043),

Glucometer Gx (Ames Division, Miles Laboratories, Etobicoke, Ontario) and