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Laboratory Evaluation of Four Reflectometers for Blood Glucose

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INTRODUCTION

Estimation of blood glucose with reflectometry has been used close to the patient during the last 20 years. With newer techniques, the reflectometers have developed into small-sized and practicable machines. At the same time the test-strip quality has been improved and combined sets been increasingly applied to home monitoring of diabetes by the patients themselves (1). Home monitoring appears easy. However, the quality of the blood glucose analysis and thus the quality of the metabolic control of the diabetics always depend on the combined performance of the set used and the skills of the analyst.

This study reports the performance characteristics of four blood glucose reflectometers with their compatible teststrips under laboratory conditions.

METHODS

Sets: The reflectometer Glucocheck SC (Orion Diagnostics, Espoo, Finland) was combined with the teststrip BM-Test Glycemie 1-44 R (Boehringer Mannheim, W-Germany). The Glucometer (Ames/Bayer, Elkhart, Indiana, USA) was combined with Dextrostix (Ames/Bayer). The Reflocheck (Boehringer/Mannheim, BM) was combined with the Reflocheck-Glucose (BM) and the Reflolux (BM) with the BM-Test Glycemie 1-44 R (BM). The measuring range for blood glucose is generally 1-22 mmol/L for the meters. The teststrips were stored and used according to the manufacturer's instructions. The reaction time in the sets studied is 60 seconds after a large drop of capillary blood has been applied. BM-Test Glycemie 1-44 R and Reflocheck Glucose are wipe-off strips that are read after another 60 seconds. Dextrostix are wash-out strips which are read in the meter immediately.

Blood specimen: Capillary blood was taken after pricking the fingertip using a minilancett from Ames/Bayer. Simultaneously, venous blood was collected into tubes containing EDTA as anticoagulant. In addition blood was sampled with Heparin as the anticoagulant and Sodiumfluoride as the antiglucolytic agent.

Samples in the hypoglycemia range were obtained from patients undergoing stimulation tests with insulin. Samples for hyperglycaemia were obtained from diabetics.

Evaluation of the sets: Accuracy was studied using a glucose hexokinase method performed in an automatic analyser as reference method. Precision was studied in duplicates. Importance of the exactness of the reaction time of the solid phase chemistry was measured by reading strips at varying times close to the stipulated 60 second reaction time. All studies were performed by trained personnel educated in clinical chemistry. Experiences with these sets under field conditions will be reported elsewhere in this volume.

Calibration

All meters are easily calibrated. In the Glucocheck, the test field is read before applying the blood. The Glucometer can be calibrated either with 2 calibration chips or 2 calibration solutions, Dextrocheck Calibrators. The Reflocheck controls a bar code on the reverse side of the strip with information on the enzyme-indicators and wavelength of the reflection used in the batch applied. For the Reflolux each strip container is equipped with a calibration strip. In addition, the Reflolux is zero-calibrated by reading the test field before applying the blood.

RESULTS

The various reflectometers are easily calibrated. The use of control solutions demonstrated that the instructions are to be followed carefully and that there should be a specific training program to ensure proper teststrip handling, especially regarding wash-out teststrips.

Table 1
Precision data C.V.%

	Hypoglycemia	Normoglycemia	Hyperglycemia
Glucocheck	-	2.8	-
Glucometer	3.1	2.9	3.6
Reflocheck	5.0	2.5	2.4
Reflolux	3.1	1.5	2.8

Accuracy of the various meters is described in Figure 1 by means of the regression equations and correlation coefficients given there. Precision is shown in Table 1. The influence of varying the reaction time of the different teststrips is depicted in Figure 2.

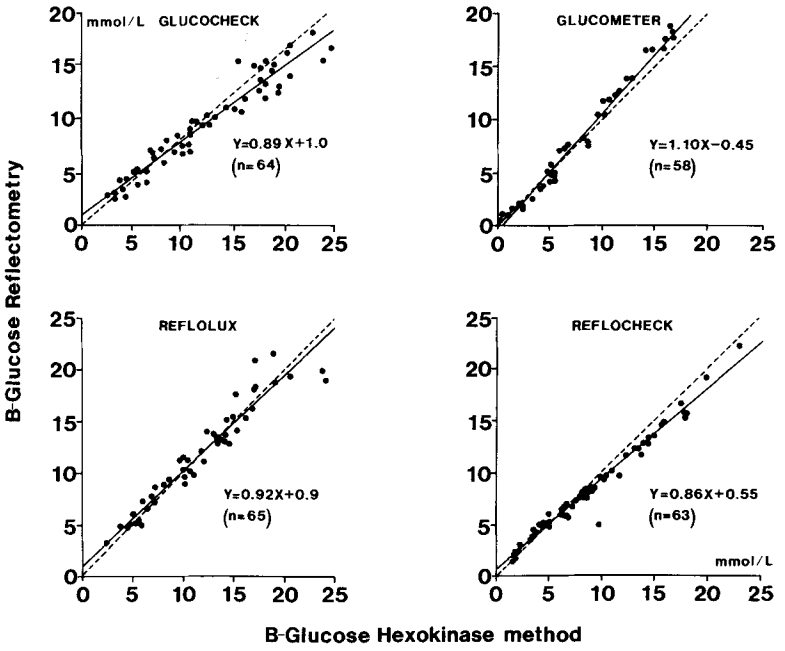

Figure 1. Accuracy of reflectometric blood glucose analyses.

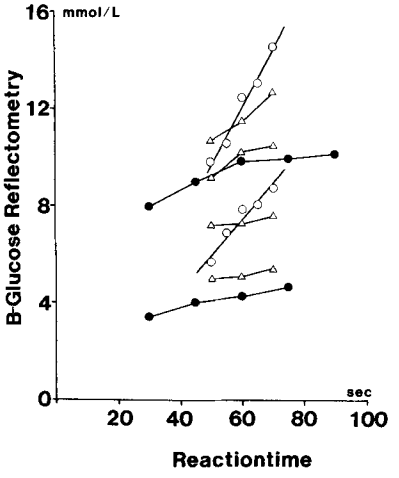

Figure 2. Effect of variation of reaction time of different test-strips on blood glucose (Dextrostix ○—○, BM-Test Glycemie ●—● and Reflocheck-Glucose △—△).

DISCUSSION

The reflectometers are easily handled and are of a technical quality which makes them suitable for ready use. As a possible improvement, I would suggest including an automatic temperature correction device since all teststrips rely on enzymes. However, the reliability of blood glucose results depends mostly on the features of the teststrip and the skills of the analyst. In the hands of trained technicians we have obtained clinically acceptable results with all the sets.

In our experience the meters seldom exhibit technical defects. Nevertheless, the most common complaint is technical malfunctioning suspected by users outside the laboratory. The most common reason is then found in reading windows encrusted with dried blood due to careless strip-handling. Therefore, the construction of the meter should be such that the window can easily be inspected when introducing the teststrip.

If we disregard incorrect storage of the teststrips prior to use, most unreliable results are due to the analyst. For example, a thrifty user might have cut the teststrip in two, resulting in insufficient testfield size for reflectometry. Most problems arise from faulty strip handling. Drops of blood which are too small are smeared over the reagent pad, leading to uneven soaking of the testpad and thus insufficient colour development. There are obviously more difficulties in handling wash-out teststrips. If the particular bottle for producing the right washing pressure on the reaction field is missing, some analysts may hold the strip under the tap and wash out the developed colour. Hence, wipe-off strips are preferred. Another reason for aberrant results is poor timing. From our colour stability test it can be inferred that teststrips with delayed reading after completed reaction time give more constant results. It might consequently be suggested that a chemical timer be placed into the teststrip to correct for smaller time differences. In order to be able to detect all sources of error the sets which are in use must be subjected to external quality control (2).

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