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Blood Glucose Monitoring outside the Hospital Laboratory

Jan Börjeson and Lilian Anzelius Collin

Department of Clinical Chemistry, Helsingborg Hospital, Helsingborg, Sweden

ABSTRACT

Glucose was determined with reflectance measurements in an attempt to introduce a quality-control program at a number of primary health care centers. A lyophilized whole blood was used as control material. Experience from two different studies shows that the precision and accuracy were not acceptable. The causes and proposed interventions are discussed.

INTRODUCTION

At primary health care centers in Sweden technically simple chemistry tests are usually performed by unskilled personnel. Most common are B-hemoglobin and B-glucose. The latter is often determined with a dry chemistry method utilizing reflectance measurements. To my knowledge it is common for all these systems that none of them includes a proper quality control material. As a consequence, there is no way of guaranteeing the validity of the test results. The Department of Clinical Chemistry in Helsingborg has an advisory function to all primary health care centers in two administrative districts. One of the main responsibilities of the laboratory is to establish an external quality assessment scheme for all the centers. In november 1984 and march 1985 a study was initiated with the aim of assessing the accuracy and precision of methods in blood glucose determination. Further its objective was to study the feasability of using a stabilized whole blood as a quality control material.

MATERIAL AND METHODS

A total of 55 primary health care centers took part in the study in november 1984 and 61 in march 1985. The participants were divided into two groups. 30 centers in 1984 and 31 in 1985 used the Boehringer Mannheims Reflomat (group A). The Ames Glucometer (group B) was used by 25 in 1984 and 30 in 1985.

The control material was commercially available, lyophilized and stabilized whole blood (Nyegaard & Co). The reconstituted blood was spiked with glucose and divided into aliquotes. It was shown to be stable for at least 5 days at room temperature. Together with written instructions it was mailed to the participants, who were instructed to make triplicate determinations and to report the results back to the laboratory.

RESULTS

The result from the study in november 1984 are shown in Fig.1. The mean and standard deviation for method group A was 6.8 $\pm$ 0.77 mmol/L and for group B 7.3 $\pm$ 1.14 mmol/L. The accuracy was evaluated as follows. Allowing a deviation of $\pm$ 10% from the mean, 76% in group A and 40% in group B fell within these limits. The precision was calculated from triplicate determinations. A 10% difference was allowed between the highest and the lowest result. 80% in group A and 52% in group B had a difference of 10% or less. In group A 63% and in group B 24% fullfilled the above limits for both accuracy and precision. See Table 1.

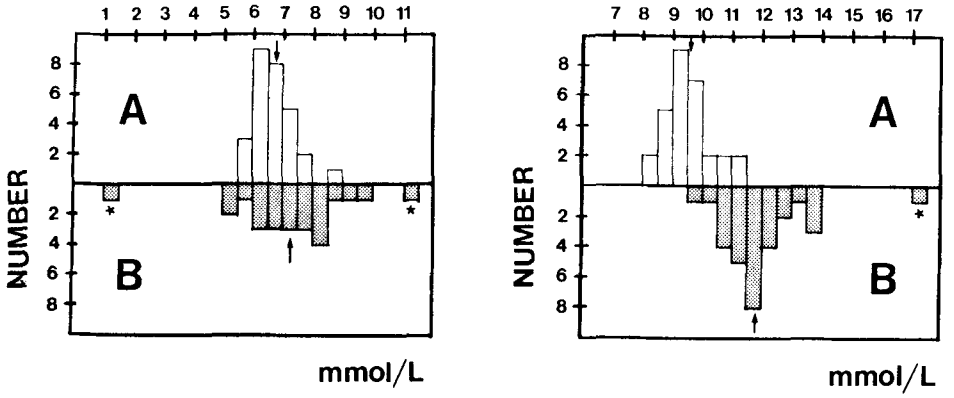

Fig 1. Distribution of blood glucose determinations 1984 (left) and 1985 (right). A (group A, Reflomat) and B (group B, Glucometer) arrows indicate the mean values for the method groups and * outliers not included in the means.

Before the study was repeated in march 1985 all machines in group B were cleaned and adjusted in order to eliminate errors of "technical" nature. No such steps were taken in group B. The results from this study are shown in Fig.1. The mean value and standard deviation were for group A 9.6 $\pm$ 0.81 mmol/L and for group B 11.9 $\pm$ 1.00 mmol/L. Corresponding values for the in-house wet chemistry determinations were 11.5 $\pm$ 0.33 mmol/L. The figures for accuracy and precision are shown in Table 1 and compared to the study from november 1984.

TABLE 1 ACCURACY AND PRECISION FOR BLOOD GLUCOSE DETERMINATION IN PRIMARY CARE HEALTH CENTERS

	PERCENTAGE PARTICIPANTS WITH ACCEPTABLE		
	PRECISION	ACCURACY	PRECISION AND ACCURACY
GROUP			
A 1984	80	76	63
B 1984	52	40	24
A 1985	84	80	74
B 1985	63	80	53

DISCUSSION

Several reports have concluded that the analytical performance of dry reagent chemistry systems does not perform well when used outside the laboratory (1, 2, 3). It is therefore of utmost importance to establish external quality-assessment schemes. There is also an urgent need to find suitable control materials for this purpose. Such material should be stable and show the same spreading characteristics on the strips as whole blood. From our data it is evident that our material introduced a bias when compared to "wet chemistry". The magnitude of the bias depended upon which reagent strip system was used. It is probably not possible to find a single control material acceptable for all reagent strips. Therefore, the manufactures ought to include a certified external quality-control material for use with their specific test strips. Our data also confirm others (1, 2, 3), that the performance, both regarding precision and accuracy, is unacceptable when used outside the laboratory. However, when used in the laboratory environment these systems have repeatedly been shown to perform well (1,4). It is probable that incorrect use is detected and avoided by establishing external quality-assessment schemes and proper training under the guidence of the hospital laboratory.

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