THE LABORATORY EVALUATION OF HOME BLOOD GLUCOSE MONITORING INSTRUMENTS

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SYNOPSIS

The use of reflectance colorimeters for home glucose monitoring has been recently advocated. We evaluated 3 such instruments in our outpatient laboratory over a 4 months' period. The results were comparable with those obtained from a reference method (Beckman-Autoanalyser) in accuracy and precision. The 3 instruments provide simple and reliable methods for home blood glucose monitoring.

INTRODUCTION

Current experimental and clinical data strongly support the relation between the quality of diabetic control and the development of diabetic complications. Most physicians today would concur with the advice of the American Diabetic Association that patients with diabetes mellitus should have blood glucose levels as close to those of the non-diabetic state as possible (1, 2). Hence, recently, the importance of 24 hr. blood glucose monitoring has been emphasised. However to make self-monitoring by patients practical, there must be available simple yet reliable methods for blood glucose estimations.

Reflectance colorimeters have been found suitable and acceptable for use by patients for home blood glucose monitoring. Our aim was to evaluate the accuracy and precision of 3 such instruments, viz. Dextrometer (Ames), Reflomat (Boehringer Mannheim) and the Royal Australian Hospital for Children (RAHC) Glucose Tester - (Fig. 1). The last instrument utilises Haemo-Glukotest strips (Boehringer Mannheim).

MATERIALS AND METHODS

(1) Accuracy

Glucose estimations were performed on 100 venous whole blood samples. The measurements were obtained with the 3 instruments concurrently. The instructions in the operating manuals for handling the 3 systems were adhered to strictly. The results of the blood glucose values were compared with those obtained from the reference method, Beckman Glucose Autoanalyser, which is the routine method of estimation in the Singapore General Hospital. It should be noted that the reference method measures plasma glucose and hence for comparison with blood glucose values, a 10% correction factor was introduced. Analyses of data were performed with the Student's t and the correlation and regression tests.

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Fig. 1 Reflectance Meters: left to right - Dextrometer (Ames), Reflomat (Boehringer Mannheim), Royal Australian Hospital for Children (RAHC) Glucose Tester.

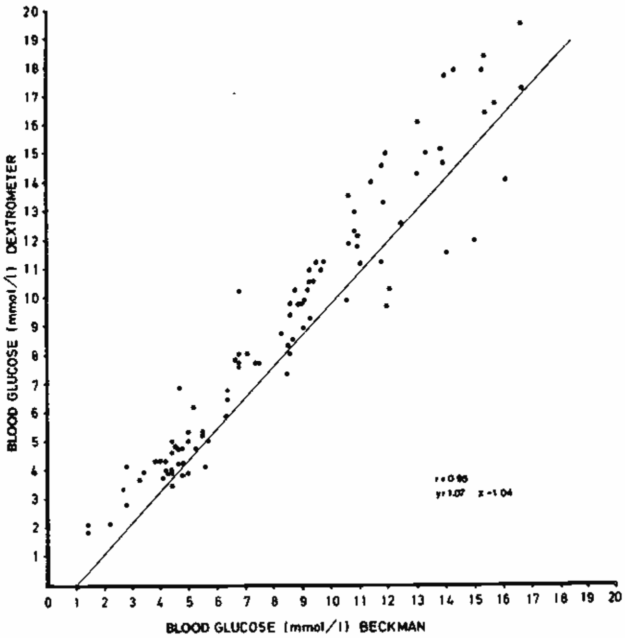

Fig. 2 Correlation between glucose determinations by Dextrometer and reference method.

(2) **Precision**

Within-run precision of the 3 instruments were next studied. Ten consecutive determinations of blood glucose were performed for a sample of whole blood with the 3 meters concurrently. The test was completed within 20 minutes to reduce the effect of glycolysis. The procedure was repeated on the same blood sample with the reference method. An estimation of the day-to-day reproducibility of the instruments was obtained from the results of 10 tests performed on one sample of plasma over 10 consecutive days. The sample of plasma was kept in aliquots at −70°C and an aliquot was removed daily for the estimation. The coefficients of variation of the results were calculated thus:

$$\frac{\text{standard deviation}}{\text{mean}} \times 100\%$$

RESULTS

(1) **Accuracy**

(a) Comparison and

(b) Correlation of the blood glucose values obtained from the instruments with those from the reference method:- the results are shown in Table 1, Figures 2, 3 and 4.

(2) **Precision**

(a) Coefficients of variability: the within-run coefficients of variation of the 3 instruments and the reference method are shown in Table 2. It is apparent that the results are comparable with those obtained from the reference method. The day-to-day coefficients of variation are shown in Table 3.

(b) Stability of strips: it should be emphasised that strict adherence to operative schedules is important in the attainment of precise results. This is illustrated by our study on the stability of the test-strips. The readings of the strips were performed at 15 second interval over a 6 minute time-frame. It is clear (Figure 5) that immediate reading of the test-strip is essential for the Dextrometer system (– as pointed out in the manufacturer's operating manual).

DISCUSSION

The precise relationship between blood sugar control and the prevalence of diabetic complications remains to be resolved. The results of recent studies suggest that good control of blood glucose may prevent or retard the development of complications of diabetes, both in animals and in man (3-6). These have led to the pursuit of 24 hr. blood glucose control (7-12). In order to achieve this, various means of measuring home blood glucose concentrations were introduced. To ensure patient's compliance, such methods have to be simple, reliable and within the economic means of the patient. The common denominator for such tests is the degree of colour change of the test-strips which is assessed visually (the conventional test-strips) or with the aid of a machine (the reflectance colorimeters). The former is obviously less reliable (semi-quantitative) when compared to the latter.

Our present evaluation showed that a high degree of accuracy was achieved by the 3 reflectance meters studied. Similar results had been reported from previous studies for the "Eyetone/Dextrostix" system (which is similar to Dextrometer) and Reflomat (13-16). The use of the RAHC Glucose Tester has been limited so far to Australia and our present study shows it compares well with the other 2 better known instru-

TABLE 1 : ASSESSMENT OF ACCURACY

		DEXTROMETER	REFLOMAT	RAHC GLUCOSE TESTER	BECKMAN ANALYSER
BLOOD GLUCOSE CONCENTRATION MMOL/L (n = 100)	MEAN	8.83*	8.66*	9.09*	8.33
	STANDARD DEVIATION (S.D.)	4.43	4.77	3.93	3.93
CORRELATION AND REGRESSION ANALYSES +	r	0.95	0.97	0.96	
	p	<0.001	<0.001	<0.001	

* NOT SIGNIFICANTLY DIFFERENT (p>0.2) COMPARED WITH THOSE OF BECKMAN AUTOANALYSER

+ BETWEEN THE INSTRUMENT AND THE REFERENCE METHOD (BECKMAN ANALYSER)

TABLE 2 : WITHIN-RUN PRECISION (n = 10)

	DEXTROMETER	REFLOMAT	RAHC GLUCOSE TESTER	BECKMAN ANALYSER
MEAN GLUCOSE CONCENTRATION MMOL/L	4.26	3.79	4.96	4.29
STANDARD DEVIATION (S.D.)	0.09	0.16	0.07	0.14
COEFFICIENT OF VARIATION C.V. (%)	2.11	4.22	1.41	3.26

TABLE 3 : DAY TO DAY REPRODUCIBILITY (n = 10)

	DEXTROMETER	REFLOMAT	RAHC GLUCOSE TESTER	BECKMAN ANALYSER
MEAN GLUCOSE CONCENTRATION MMOL/L	5.52	4.48	5.46	4.04
STANDARD DEVIATION (S.D.)	0.56	0.48	0.43	0.20
COEFFICIENT OF VARIATION C.V. (%)	10.14	10.71	7.88	4.95

ments. The procedures for the use of the reflectance meters are simple and rapid. However, considerations must be given to the significant potential for human errors of imprecise timing and inconsistent washing/wiping for all 3 instruments. Certain blood constituents may potentially interfere in the estimation of blood glucose but in practice this was not a major problem (17).

The instruments are small and portable, suitable for use by patients at home or at place of work. The Dextrometer and RAHC Glucose Tester can be operated by battery or mains-power whilst the Reflomat by mains-power only. The cost of Dextrometer is S$773 whilst that of Reflomat is S$1440. The reagent strips used by both instruments are about S$1 each. Quotation for the Australian instrument is not available just now.

It should be emphasized that in this study the instruments were assessed in the laboratory. It remains to be established whether comparable performance could be attained by patients in their homes. Studies in the West (7-9, 18) have shown that patients with limited education could achieve accurate readings. Home glucose monitoring has the additional spin-off in motivating patients to participate actively in the management of their own ailments.

Many other factors besides sustained hyperglycaemia may be responsible for the pathogenesis of diabetic complications. They include genetic factors (19), abnormalities of platelet functions, other circulating metabolites, immune complexes, focal ischaemia and local abnormal tissue metabolism. Nevertheless, WHO in its 1980 report (6) advised that metabolic normoglycaemia be achieved in the hope of preventing or retarding the developing of complications of diabetes.

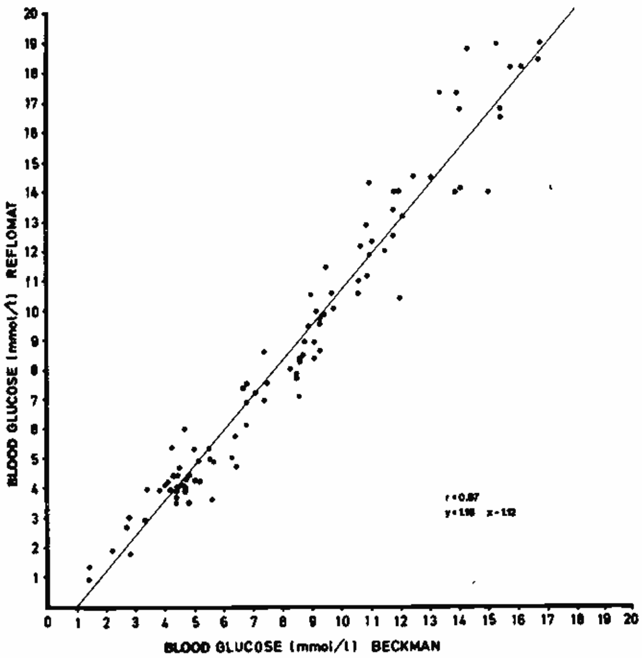

Fig. 3 Correlation between glucose determinations by Reflomat and reference method.

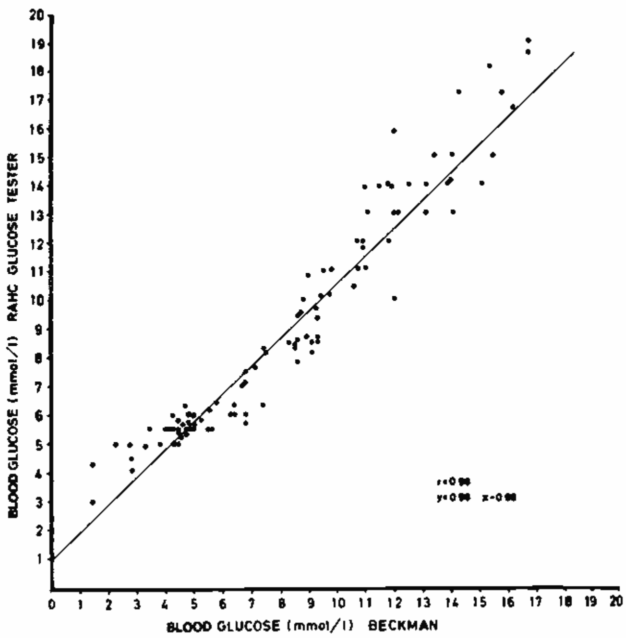

Fig. 4 Correlation between glucose determinations by RAHC Glucose Tester and reference method.

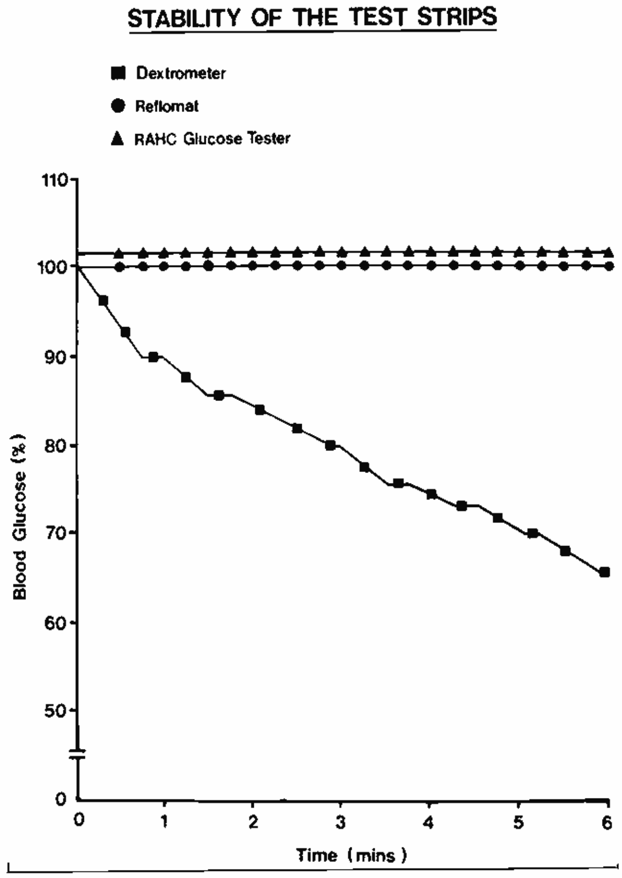

Fig. 5 Stability of the test strips and time

REFERENCES

1. Cahill GF, Etzwiler DD, Freinkel N.: Blood glucose control in diabetes. Diabetes 1976; 25: 237-239.
2. Cahill BF, Etziler DD, Frienkel N.: "Control" and diabetes. N. Engl. J. Med. 1976; 294: 1004-1005.
3. Tchobroutsky G: Relationship of diabetic control to development of microvascular complications. Diabetologia, 1978; 15: 143-152.
4. Job D, Eschwege E, Guyot-Argenton C, Aubry JP, Tchobroutsky G.: Effect of multiple daily insulin injections on the course of diabetic retinopathy. Diabetes 1976; 25: 463-469.
5. Eschwege E, Job D, Guyot-Argenton C, Aubry JP, Tchobroutsky G.: Diabetologia 1979; 16: 13-15.
6. WHO Expert Committee on Diabetes Mellitus, Second Report, WHO Tech Rep Ser 1980; No. 646.
7. Sonksen PH, Judd SL. Home monitoring of blood glucose: method of improving diabetic control. Lancet 1978; 1: 729-732.
8. Walford S, Gale EAM, Allison SP, Tattersall RB. Self-monitoring of blood glucose: improvement of diabetic control. Lancet 1978; 1: 732-735.
9. Peterson CM, Jones RL, Duphis A, Levine BS, Berstein R, O'shea M. Feasibility of improved blood glucose control in patients with insulin-dependent diabetes mellitus. Diabetes Care 1979; 2: 329-335.
10. Tattersall RB. Home blood glucose monitoring. Diabetologia 1979; 16: 71-74.
11. Paise RB, Bredshaw P, Hartog M. Home blood glucose concentrations in maturity onset diabetes. Br Med J 1980; 280: 596-598.
12. Howe Davies S, Holman RR, Phillips M, Turner RC. Home blood sampling for plasma glucose assay in control of diabetes. Br Med J. 1978; 2: 596-598.
13. Scherstein B, Kuhl C, Hillender A, Ekman R. Blood glucose measurement with Dextrostix and new reflectance meter. Br. Med J. 1974; 3: 384-387.
14. Davis A. Evaluation of an improved reagent strip system for measuring blood glucose. American Journal of Medical Technology 1976; 42: 18-21.
15. Javett R, Keane H, Hardwick C. "Instant" blood sugar. Measurements using Dextrostix and a reflectance meter. Diabetes 1970; 19: 724-726.
16. Brunton WAT, Steel JM, Percy-Robb IW. Clin. Chim. Acta 1977; 75: 359-364.
17. Stewart TC. Evaluation of a reagent-strip method for glucose in whole blood, as compared with a hexokinase

method. Clinical Chemistry 1976; 22: 74-78.

18. Ikeda Y, Tajima N, Nimanic N, Ide Y, Yoroyama J, Abe M. Pilot study of self-measurement of blood glucose using the Dextrostix - Eyetone system for juvenile onset diabetes. Diabetologia 1978; 15: 91-93.

19. Leslie RDG, Barnett AH, Pyke DA. Chlorpropamide alcohol flushing and diabetic retinopathy. Lancet 1979; 1: 997-999.