

HOME BLOOD GLUCOSE MONITORING WITHOUT A METER (HAEMO-GLUKOTEST 20-800 TEST STRIP): THE SINGAPORE EXPERIENCE

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SYNOPSIS

Home blood glucose monitoring is now an accepted tool for the optimization of diabetes control. The Haemo-Glukotest 20-800 (Boehringer-Mannheim BM) is a second generation reagent strip for semiquantitative visual assessment of blood glucose. It has two colour test zones which reads a wider range of blood glucose concentrations.

We studied 22 local diabetic subjects using the BM sticks. A total of 212 tests were obtained. The results were compared with the "stored" Reflotest strip" method performed simultaneously by the patients. One hundred blood glucose estimations were similarly assessed by two trained hospital staff.

Our results showed that blood glucose levels estimated by the Haemo-Glukotest strips are of sufficient accuracy for clinical use. The overall correct results obtained were 83% and 96% for the patients and hospital staff respectively. The strip provides a simple, rapid, convenient and reliable method of self-measurement of blood glucose without the need of incurring the cost of a reflectance meter. It plays an important role in allowing home monitoring of blood glucose to be within the means of a wider group of diabetic patients.

INTRODUCTION

Diabetes mellitus is associated with the morbidity of long-term complications of the disease viz.: retinopathy, neuropathy and nephropathy. There is impressive evidence that poor blood glucose control plays an important causal role in the development of these complications⁽¹⁾. Hence, the renewed interest towards good control of blood glucose^(2, 3) and the use of systems for home blood glucose monitoring^(4, 5).

Home blood glucose monitoring is the process whereby the patient assess his own blood glucose levels throughout 24 hours. This provides information about the pattern of daily blood glucose fluctuations which helps the physician to advise on adjustment in treatment. Various systems for self-monitoring of blood glucose have been described. These systems require the use of reagent strips alone (semiquantitative) or in conjunction with reflectance meters (quantitative). The latter technique, although precise and accurate is relatively expensive and not widely applicable^(6, 8). Improvement in the quality of reagent strips for visual performance is important as it would make self-measurement of blood glucose feasible to a larger number of diabetic subjects. The Haemo-Glukotest 20-800 (Boehringer Mannheim) test strip is a second generation blood glucose reagent strips with two-colour test zones which reads a wider range of blood glucose concentrations. It has been found to give results of acceptable accuracy⁽⁹⁻¹¹⁾ for the day to day use by the patients at home.

The aim of our study is to assess the reliability of the Haemo-Glukotest 20-800 strip as a method of home monitoring of blood glucose for our local diabetic patients.

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TABLE 1: BLOOD GLUCOSE RESULTS WITH THE HAEMO-GLUKOTEST 20-800 STRIPS IN RELATION TO THE STORED REFLATEST STRIPS METHOD (22 PATIENTS)

Haemo-Glukotest 20-800 Reading (mmol/L)	Number of Observations	Reflotest Method (mean and range) (mmol/L)	Number Correct	% Correct
1.1	0	-	-	-
2.2	9	5.4 (4.5- 6.8)	0	0
4.4	18	6.1 (3.5- 7.8)	13	72
6.7	52	7.5 (5.6-13.0)	47	90
10.0	73	11.1 (6.3-16.8)	53	75
13.3	55	16.1 (10.6-20.0)	55	0
22.2	5	20.0 (20 mmol/L)	5	0
Total	212		175	83

PATIENTS AND METHODS

Twenty-two motivated and educated diabetic subjects were selected from our outpatient's clinic. Their mean age was 32 years (range 17-63 years). There were 15 males and 7 females.

(a) Haemo-Glukotest 20-800 Strips Method

Blood glucose estimations were performed by the patients at home with Haemo-Glukotest strips (Figure 1) according to the manufacturer's instructions. The strip has two-colour test zones which reads eight pairs of colours corresponding to blood glucose values of 1.1-44.4mmol/L (20-800 mgm/DL) [Table I]. When the test colour of the strip did not correspond exactly to any of the eight blood glucose values, the patients were taught to choose the value with the nearest match.

(b) Stored Reflotest Strips Method

Simultaneously with the performance of the Haemo-Glukotest strips method, the patients estimated their blood glucose levels using the stored Reflotest Strips method^(12, 13) which served as our reference method. This method makes use of the Reflotest strips (Boehringer Mannheim) which remains stable when stored under suitable conditions. The patient performs the blood test as usual by applying a drop of blood from a finger prick onto the Reflotest strip. Instead of reading the strip immediately with the reflectance meter (Reflomat), he stores the strip in a small dessicator container which keeps the strip dry. This container is the receptacle in which the Reflotest strips are marketed. He then brings the container with the strip in-situ for reading with the Reflomat at our outpatient's clinic the following day.

(c) Assessment of Observer-s Variation

Two trained hospital staff independently carried out the same procedures on 50 venous blood samples obtained from the outpatient clinic.

Interpretation of Results

The test value of the 20-800 strips was compared with the value obtained by the reference method. If the corresponding reference value fell within one colour step from the test reading then such a test reading was deemed correct.

RESULTS

(a) Accuracy

The 22 patients carried out 212 pairs of blood glucose estimations. The results obtained with the Haemo-Glukotest 20-800 strips in relation to the reference method are shown in Table I. The overall correct results obtained were 83%. Table 2 shows the results of the 100 pairs of blood glucose estimations obtained by the two hospital staff. The overall correct readings were 96%.

(b) Observer's variation

The two hospital staff disagree on 11 of the 50 paired blood glucose estimations when the 20-800 strips were read to the nearest colour block, giving an observers' variation of 22%. However, when interpretation was made between the two adjacent colour blocks to give intermediate values, they disagree on only 5 of the 50 observations ie. 10% observer's variation.

(c) Age and sex influence

Subjects who obtained 80% or more correct readings were classified as good performers and those with less than 80% were poor performers. Table 3 shows the comparison of the good performers with the poor performers according to age and sex. The results shows that both factors have no significance on the subjects' performance with the test strips.

DISCUSSION

This study showed that the Haemo-Glukotest 20-800 strip is reliable method for home blood glucose monitoring in our group of local diabetic subjects. A high degree of accuracy is obtained in the important normoglycaemic range of

TABLE 2: BLOOD GLUCOSE RESULTS WITH THE HAEMO-GLUKOTEST 20-800 STRIPS IN RELATION TO THE REFERENCE METHOD (2 HOSPITAL STAFF)

Haemo-Glukotest 20-800 Reading (mmol/L)	Number of Observations	Reflotest Method (mean and range) (mmol/L)	Number Correct	% Correct
1.1	0	-	-	-
2.2	16	3.6 (2.9- 4.8)	13	81
4.4	25	4.2 (2.9- 6.1)	25	100
6.7	19	6.7 (5.1- 7.8)	19	100
10.0	9	10.0 (8.2-11.9)	9	100
13.3	14	16.0 (11.9-20.0)	14	100
22.2	17	19.4 (14.9-20.0)	17	100
Total	100		96	96

TABLE 3: COMPARISON OF GOOD PERFORMERS (80% OR MORE CORRECT READINGS) WITH POOR PERFORMERS (LESS THAN 80% CORRECT READINGS) ACCORDING TO AGE AND SEX

AGE

	Good (n = 16)	Poor (n = 6)	P
x Age	35	23	N.S.

SEX

	Good	Poor	P
Male	10	6	N.S.
Female	5	1	

4.4-10.0 mmol/L. Less accurate results were obtained in the low blood glucose values of below 4.4 mmol/L. One reason for this is that the Reflotest strip used in our study is not suitable for measurement of blood glucose below 3 mmol/L and there is a tendency for hypoglycaemic values to be over-read when checked 24 hour or more later. Better results would have been obtained for the low blood glucose range if the tests were performed with the Reflotest-Hypoglycaemic strips.

The 20-800 strip has a great advantage, compared to self-monitoring systems where the use of a reflectance meter is essential, of being much more economical. The cost of a 20-800 strip is about S\$1 whereas the initial cost for a meter is about \$475 (Dextrometer, Ames) to S\$1,400 (Reflomat). The difficulty, however, with visual estimation by the 20-800 strip is that it lacks the objectivity compared to a reflectance meter. In our study, the patients tend to underestimate their blood glucose values, especially in the higher range of 10 mmol and above. This finding has also been reported by other workers¹⁴. Neither age nor sex has a significant influence in our patients' visual performance with the 20-800 strip, and Graham et al¹⁵ also found that colour vision and diabetic retinopathy did not affect the reading of the strips.

In conclusion, the results of this study showed that the Haemo-Glukotest 20-800 strip is an acceptable method for patient's self-monitoring of blood glucose by virtue of its economy, simplicity, convenience and reasonable accuracy. Moreover, the good results obtained by the two trained hospital staff indicate that it could be used as a method for rapid blood glucose estimations in the outpatient clinic and in emergency wards.

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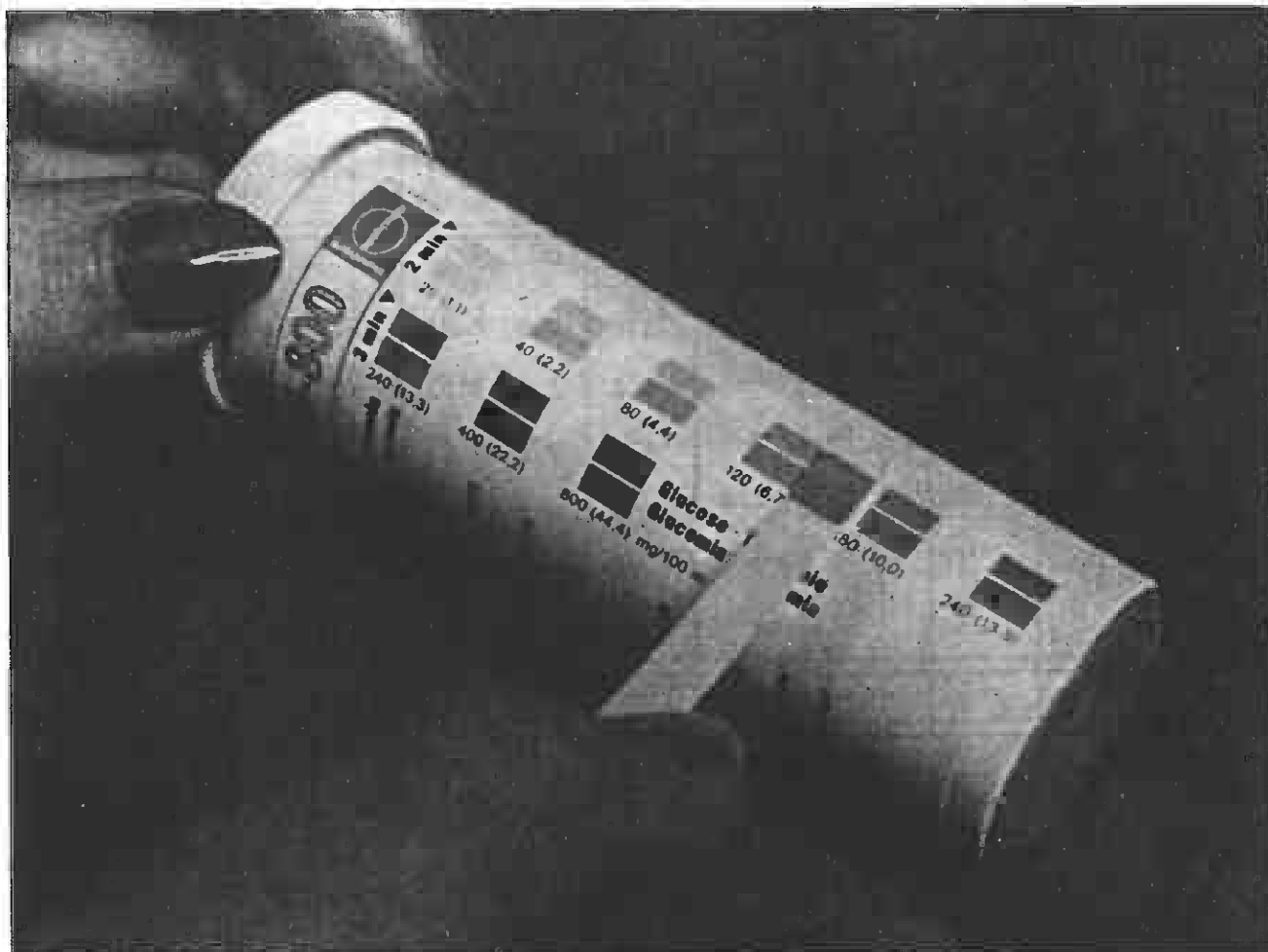


Figure 1: Visual assessment of blood glucose concentration with the Haemo-Glukotest 20-800 strips.

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