Accuracy of blood glucose concentrations determined by four visually read reagent strips

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SUMMARY
Two new reagent strips have recently been introduced for blood glucose measurement by direct visual reading. Results obtained with these strips (Glucostix and Hypogard GA) were compared with those obtained using other commonly employed strips (BM-Test-Glycemie 1–44 and Visidex II) and a standard laboratory method. Blood glucose estimations were performed on samples of venous blood drawn from 125 patients attending the diabetic clinic using each of the four strips and the laboratory method. Results obtained with the strips correlated with the laboratory values as follows: BM-Test-Glycemie 1–44, \( r = 0.93 \); Glucostix \( r = 0.93 \); Hypogard GA \( r = 0.87 \) and Visidex II \( r = 0.92 \). The lower correlation with Hypogard GA reflected consistent under-estimation of the laboratory value (slope of regression line = 0.63). Readings in error by 20% or more were: BM-Test-Glycemie 1–44, 14%; Glucostix, 15%; Hypogard GA, 31%; and Visidex II, 14%. With Hypogard GA strips, 57% of readings above 16 mmol/l were inaccurate. We conclude that Hypogard GA strips cannot be recommended for direct visual reading. Acceptable results may, however, be obtained using the other three strips.

Reagent strips allow reasonably accurate determinations of blood glucose concentrations when used with a reflectance meter. Nevertheless many diabetic patients prefer to read the reagent strips visually. This method avoids the problems associated with meter calibration, is cheaper and also is more portable. Direct visual readings with BM-Test-Glycemie 1–44 (Boehringer Corporation) and Visidex II (Ames) have been shown to be acceptable in the hands of medical and technical personnel. Recently two new reagent strips have been marketed, Hypogard GA (Hypogard UK Ltd) and Glucostix (Ames), and it is claimed that they are also suitable for direct visual reading. To test the validity of these claims, we have compared results obtained using the newer strips with readings from BM-Test-Glycemie 1–44 and Visidex II and with a standard laboratory method.

PATIENTS AND METHODS
Blood was removed by venepuncture from 125 patients routinely attending the diabetic clinic. A portion of each sample was sent to the laboratory for glucose determination by a glucose oxidase method (Glucoroder·E, Analytical Instruments Company). External quality control of this method takes place as...
part of the UK Prospective Diabetes Study. Over the period of the study mean bias of readings against external standards was 0.4% with a between-batch coefficient of variation of 2.2%.

A drop of blood from each sample was also placed, directly from the syringe, on to one of each of the four reagent strips. Strips were prepared according to the manufacturer's instructions. Blood was removed from two of the strips (Hypogard GA and BM-Test-Glycemie 1-44) by a wiping technique after 30 and 60 seconds respectively. Blood was removed from both of the other strips (Visidex II and Glucostix) after 30 seconds by a blotting technique.

Two doctors attended each session, one preparing and reading the 'wiped' strips and the other preparing and reading the 'blotted' strips. Blood was applied to each of the strips in random order and the strips were read in random order. The person who had read the 'blotted' strips at one session would read the 'wiped' strips at the next. Readings were acquired at five different sessions. At one session Visidex II strips were not used due to temporary unavailability at the clinic.

We attempted to estimate blood glucose values which lay between colour blocks to the nearest 0.5 mmol/l for values below 20 mmol/l. This gave the observers flexibility in their interpolations, although we recognised that visual reading of strips is not designed to give such precise readings particularly at higher glucose concentrations. Estimation to the nearest 0.5 mmol/l also helped us to overcome any difficulty caused by the different intervals between colour blocks used for visual reading of the various strips.

RESULTS

Blood glucose values obtained using reagent strips are plotted against corresponding laboratory values in the Figure. Readings with each of the strips

![Blood glucose values obtained with reagent strips ('y' axes) plotted against corresponding laboratory values ('x' axes). Regression lines are also drawn.](image)

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correlated reasonably closely with laboratory values (BM-Test-Glycemie 1–44 \( r = 0.93 \), Glucostix \( r = 0.93 \), Hypogard GA \( r = 0.87 \), Visidex II \( r = 0.92 \)). With Hypogard GA strips the correlation coefficient was lower than with the other strips. In addition, readings with Hypogard GA strips were consistently lower than the corresponding laboratory values (regression line slope = 0.63).

We examined separately results in the low, middle and high ranges. In order to illustrate how consistently the strips performed over our different ranges, (arbitrarily chosen as < 8, 8–16 and > 16 mmol/l) readings which were inaccurate by 20% or more are shown in the Table. BM-Test-Glycemie 1–44 strips gave few incorrect results for values less than 16 mmol/l but were unreliable above this level. Glucostix and Visidex II were less reliable than BM-Test-Glycemie 1–44 in the low and middle ranges but were relatively accurate in the high range. With Hypogard GA strips, inaccurate results were relatively frequent in the low and middle ranges but very frequent (more than 50%) in the high range. Most discrepancies with BM-Test-Glycemie 1–44 and Hypogard GA in the high range were underestimates of the laboratory value, whereas with the other strips there were both over- and underestimates.

**TABLE**

Results in error by > 20%

| Range            | <8   | 8–16 | >16  | Overall |
|------------------|------|------|------|---------|
| BM Glycemie 1–44 | 4 (15)| 5 (7 )| 8 (29)| 17 (14) |
| Glucostix        | 6 (22)| 10 (14)| 3 (11)| 19 (15) |
| Hypogard GA      | 7 (26)| 16 (23)| 16 (57)| 39 (31) |
| Visidex II       | 4 (19)| 6 (10)| 5 (19)| 15 (14) |

Results are expressed as numbers in error by 20% in each blood glucose range and in parentheses as percentage results in error.

Only 106 results were available for Visidex II.

**DISCUSSION**

All of the reagent strips were simple to use and could provide a result within two minutes. Both observers felt that the ‘wipe’ technique (Hypogard and BM-Test-Glycemie 1–44) was easier and less messy.

The tendency for Hypogard GA strips to give inappropriately low readings does give rise to concern: in several cases errors in management might have resulted if treatment had been based on the reagent strip results alone. The manufacturers have suggested that the underestimation may be caused by excessive pressure, applied during wiping blood off the strips, leading to removal of reagent from the surface. If this is the case, it is likely that patients will make a similar mistake and we would suggest that these strips are not the best choice for visual reading.

There was little to choose between the other three strips. Over the 0–16 mmol/l range BM-Test-Glycemie 1–44 strips were perhaps superior, whereas above 16 mmol/l significant mistakes were frequent. Visidex II and Glucostix were a little less reliable in the lower ranges but proved quite accurate in the higher range.

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Blood glucose reagent strips

It should not be forgotten that these results were obtained under relatively ideal conditions. When testing their own blood glucose in everyday life, patients may be in a hurry or have difficulty obtaining an adequate sample of blood. Others may have visual impairment. In practice therefore a greater number of inaccurate readings can be expected.5

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