Comparative Accuracy of Portable Blood-Glucose Monitors

G. RAYMAN, MB, MRCP(UK),* *Research Registrar,*
M. ELLWOOD-RUSSELL, SRN, *Diabetic Education Sister,*
P. SPENCER, BSc, MB, *Clinical Assistant to the Diabetic Unit,*
M. PRENTICE, BSc, MRCP(UK), *Medical Registrar,*
S. ROUSE, BSc, *Biochemist, Department of Chemical Pathology,*
P. WISE, PhD, FRCP, *Consultant Endocrinologist, Department of Endocrinology, Charing Cross Hospital, London.*

The high morbidity and mortality resulting from the long-term diabetic complications of retinopathy, nephropathy and lower limb ischaemia make prevention of these complications the major objective of diabetes management. Increasing experimental and clinical evidence suggests that maintenance of normal blood glucose levels can prevent or delay the development of complications[1-3]. Accordingly, most diabetologists aim to achieve as good blood glucose control as possible in the young insulin-dependent diabetic who is at greatest risk, and in the pregnant diabetic woman where the prognosis for the fetus is closely related to the degree of control[4]. Home blood-glucose monitoring has been shown to improve control, and the majority of patients find blood glucose monitoring preferable to urinalysis[5, 6]. The enthusiasm for home blood-glucose monitoring led to the development of small, battery-operated, portable reflectance monitors employing Dextrostix glucose-oxidase reagent strips. The performance of these early portable monitors has been questioned in several studies [7-9]: more recently, several new monitors have been introduced for use with either Dextrostix or 'BM-Test Glycemie' glucose-oxidase reagent strips. Although originally intended for patient use, such monitor/strip systems are finding increasing use in hospital practice to provide the quick, convenient blood glucose results needed when managing insulin infusion systems and for routine blood glucose estimation in diabetic wards and out-patient departments.

To fulfil such a variety of uses the ideal monitor/strip system must be simple to use and accurate at all blood glucose values within the range stated by the manufacturers. This study assesses the accuracy of the presently available portable monitor/strip systems over three blood glucose ranges (0-6, 6-12 and >12 mmol/litre) as well as over the entire operating range (0-22 mmol/litre).

*Requests for reprints to Dr G. Rayman, Endocrine Unit, Charing Cross Hospital, Fulham Palace Road, London W6 8RF.

Material and Methods

Table 1 shows the five monitor/strip systems which were assessed.

Table 1.

Monitor	Glucose-oxidase reagent strip
Glucometer	Dextrostix
Hypocount II 'A'	Dextrostix
Hypocount II 'B'	BM-Test Glycemie
Glucochek 'A'*	Dextrostix
Glucochek 'B'*	BM-Test Glycemie

*Authors' own notation to distinguish between Glucochek systems.

Calibration of Monitors

The Glucometer is calibrated using either calibration chips or high and low (16.67 and 2.78 mmol/litre) calibration solutions. The latter method is recommended by the manufacturers, as it allows for variation between batches of strips, differences in technique between operators and variations in environmental temperature. Calibration is recommended after a change of battery or batch of Dextrostix, after an ambient temperature change of more than 5°C and when used by a new operator. Despite the advantage of this calibration system, the large variation in developed colour with the 16.67 mmol/litre solution (16.7 ± 1.2 mmol/litre; mean ± 2 SD; n = 15) can cause considerable uncertainty in the calibration. Such errors are not detected using the check solution (5.6 mmol/litre), as this is closer to the lower end of the range where the developed colour is more consistent. For this study, correct calibration at the high point was assumed if the mean of 15 measurements using the high calibration solution was 16.7 ± 0.1 mmol/litre.

Calibration of the Glucochek monitors is set at the time

of manufacture; there is no additional procedure to correct for variations in the strips, etc. As with the Hypocount systems, a checkstrip is provided which can be used to detect any drift in calibration. The Hypocount system corrects for between-batch variation in the background colour of an unused strip by a self-calibration procedure performed just prior to the application of the blood sample.

For each monitor/strip system one operator performed 105 blood glucose measurements using two representative instruments (70 and 35 measurements each). Venous blood samples for glucose measurement were obtained from patients attending a routine diabetic clinic. Part of the sample was assayed within one minute of venesection by the meter method, the remainder being assayed by a reference laboratory method (Auto-analyser I continuous flow glucose oxidase/aminophenazone with dialysis; the between-batch coefficient of variation is 1.7 per cent at 5.01 mmol/litre and is 1.4 per cent at 17.06 mmol/litre).

To extend the range, additional samples were obtained from patients known to be hyperglycaemic and from patients undergoing insulin-induced hypoglycaemia in the course of pituitary function testing.

Results

Table 2 shows the analysis of the results obtained for each pair of individual monitor/strip systems over the three blood glucose ranges and also over the entire range.

Table 2. Statistical comparison of the five meter/strip systems. r = correlation coefficient. Sy.x = standard deviation from regression.

Monitor	r	Regression Equation Intercept	Slope	Sy.x mmol/l
Range 0-6 mmol/litre				
Glucometer	0.97	−0.19	1.02	0.35
Hypocount 'A'	0.94	0.12	0.98	0.56
Hypocount 'B'	0.93	0.91	0.85	0.51
Glucochek 'A'	0.86	0.59	0.71	0.60
Glucochek 'B'	0.83	1.64	0.64	0.57
Range 6-12 mmol/litre				
Glucometer	0.87	0.61	0.99	0.98
Hypocount 'A'	0.88	−2.90	1.35	1.10
Hypocount 'B'	0.91	0.09	1.01	0.69
Glucochek 'A'	0.86	−1.83	1.19	1.12
Glucochek 'B'	0.86	−1.27	1.34	1.10
Range >12 mmol/litre				
Glucometer	0.92	5.43	0.64	0.97
Hypocount 'A'	0.79	6.46	0.57	1.71
Hypocount 'B'	0.97	2.26	0.86	0.81
Glucochek 'A'	0.89	1.74	0.78	1.47
Glucochek 'B'	0.88	10.14	0.41	0.89
Range 0-26 mmol/litre				
Glucometer	0.98	1.16	0.88	1.14
Hypocount 'A'	0.97	0.92	0.89	1.57
Hypocount 'B'	0.99	0.64	0.95	0.72
Glucochek 'A'	0.97	0.68	0.84	1.32
Glucochek 'B'	0.95	2.48	0.83	1.77

Figs. 1-5 show scattergrams in which results obtained with individual monitor/strip systems are plotted against laboratory blood glucose.

Glucose Range 0-6 mmol/litre. In this range the Glucometer produced results which correlated closest with the laboratory blood glucose values (correlation coefficient (r) = 0.97) and also gave the narrowest scatter of results about the regression line (standard deviation from regression, Sy.x = 0.35 mmol/litre). Good correlations were also obtained with Hypocount 'A' and 'B' monitors: however, the latter, like the Glucochek 'B', over-estimated blood glucose values below 3 mmol/litre, whereas all three Dextrostix-based systems reliably detected hypoglycaemic samples.

Glucose Range 6-12 mmol/litre. The Hypocount 'B' monitors correlated best with laboratory blood glucose and gave the smallest scatter of results in this range (r = 0.911, Sy.x = 0.69 mmol/litre). Correlation coefficients were lower for the Dextrostix-based systems, which also gave a wider scatter of results at the upper end of this range. The Glucochek 'B' monitors consistently over-estimated blood glucose in this range.

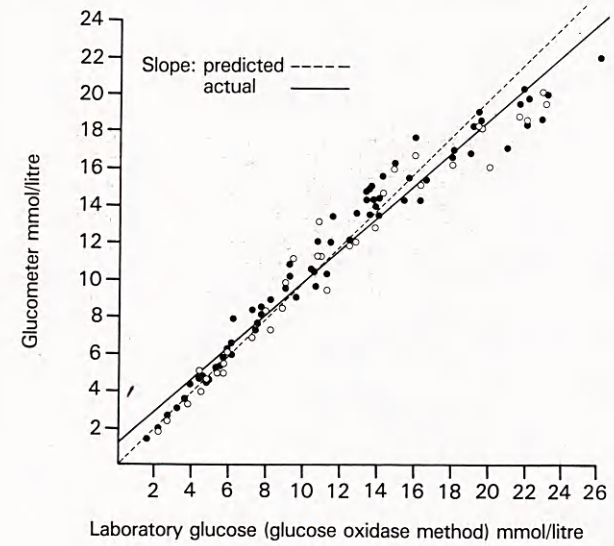
Glucose Range > 12 mmol/litre. In this range, the Hypocount 'B' monitors correlated best with laboratory values, gave the smallest standard deviation from regression and a regression slope closest to unity (r = 0.97, Sy.x = 0.81 mmol/litre, slope = 0.86). Results with the Dextrostix-based systems were more widely scattered, as suggested by the larger standard deviation from regression (0.97-1.71 mmol/litre), and their regression slopes, like that of the Glucochek 'B' monitors, were less than 0.80. The pair of Hypocount 'A' monitors differed in their readings in this range, suggesting a difference in the calibration set at the time of manufacture.

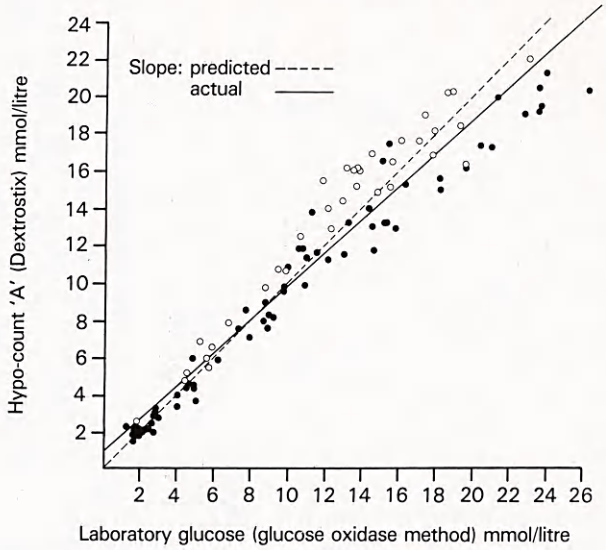
Glucose Range 0-26 mmol/litre. Since on occasions a meter reading was obtained despite a laboratory blood glucose above 22 mmol/litre, the range examined extended to 26 mmol/litre. Over this range the Hypocount 'B' system gave a high correlation coefficient and a regression equation closest to that of the line of identity (r = 0.99, y = 0.64 + 0.95x, Sy.x = 0.72 mmol/litre).

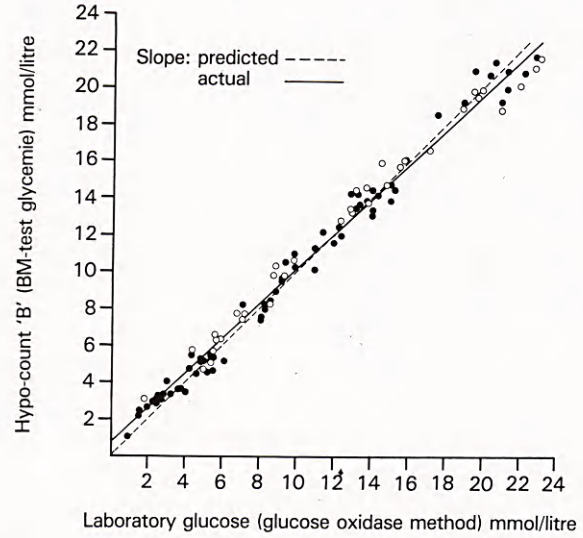
Discussion

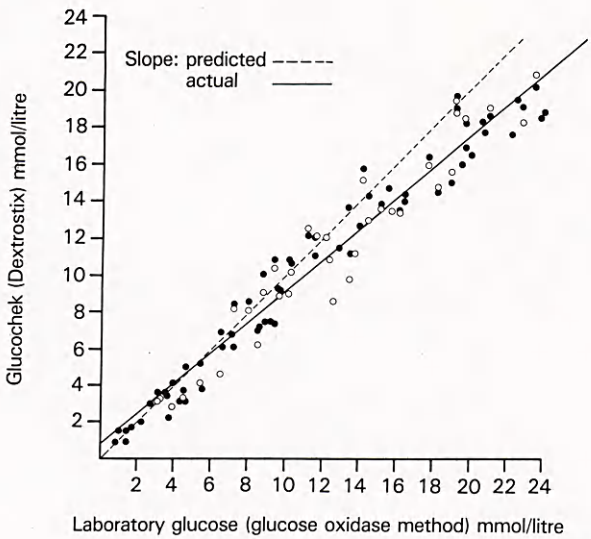
The study shows that the performance of an individual monitor/strip system is not uniform; thus calculation of a single correlation coefficient over the whole range of blood glucose values for each monitor, as assessed in some previous studies [9, 10], may not be the most satisfactory method of comparing systems.

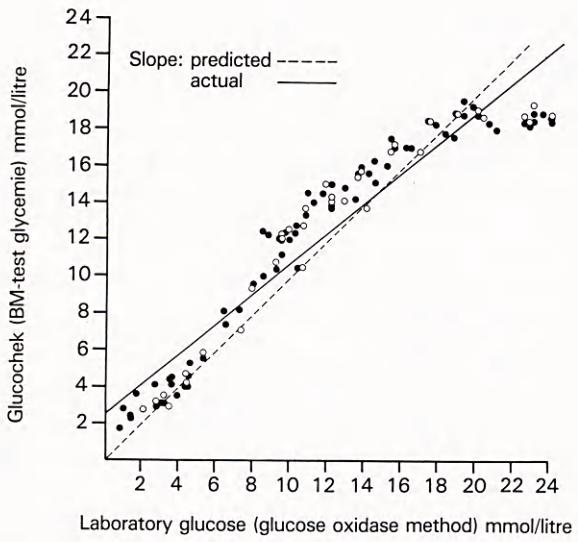
Using the criteria of correlation coefficient, slope and intercept of regression line, and standard deviation from regression, the Glucometer performed best at the lowest range (0-6 mmol/litre) whereas the Hypocount 'B' performed best in the middle (6-12 mmol/litre) and high (>12 mmol/litre) ranges. Above 12 mmol/litre those











Figs. 1-5. *Scattergrams of blood glucose results for the five meter/strip systems plotted against laboratory blood glucose. The solid lines are the actual regression lines; the broken lines are the lines of identity.*
Solid and open circles depict measurements by each of a pair of meters.
Conversion: SI to traditional units—Glucose: 1 mmol/litre = 18mg/100ml.

systems employing Dextrostix gave a larger scatter of results and a regression slope of less than 0.8: above 18 mmol/litre they frequently under-estimated blood glucose.

The object of this study was to assess the accuracy of the systems when used strictly in accordance with the manufacturers' instructions, rather than to assess ease of use, hence a single experienced operator performed all the measurements. There are several other factors determining the choice of a particular monitor[11]. To date there have been no studies assessing patients' preference or ability to use the newer Hypocount and Glucometer systems. As a general comment, however, on the systems examined, the Glucochek system was found to be the simplest to use and the most portable; both these advantages are probably offset by the lack of a calibration system. The Hypocount systems, which correct for variations in unused strip colour, were simpler to use than the Glucometer, which requires two-point calibration that is time-consuming and subject to error.

This study suggests that the Hypocount 'B' would be preferred for general ward use and home blood glucose monitoring because of its relative ease of use and its accuracy over a wide range of blood glucose values, provided that readings below 3 mmol/litre are regarded as potentially hypoglycaemic. When used by trained staff, the Glucometer, because of its greater accuracy below 6 mmol/litre, would be the preferred meter for managing insulin infusion systems.

References

1. Fox, C. J., Darby, S. C., Ireland, J. T. and Sönksen, P. H. (1977) *British Medical Journal,* **2,** 605.
2. Engerman, R., Bloodworth, J. M. B. and Nelson, S. (1979) *Diabetes,* **26,** 760.
3. Job, D., Eschwegne, E., Guyot-Argenton, C. *et al.* (1976) ibid., **25,** 463.
4. Ylinen, K., Raivio, K. and Teramo, K. (1981) *British Journal of Obstetrics and Gynaecology,* **88,** 961.
5. Sönsken, P. H., Judd, S. L. and Lowy, C. (1978) *Lancet,* **1,** 729.
6. Walford, S., Gale, E. A. M., Allison, S. P. and Tattersall, R. B. (1978) ibid., **1,** 732.
7. Pantin, C. F. A., Brown, E. A., Bihari, D. and Bloom, A. (1980) *Postgraduate Medical Journal,* **56,** 757.
8. Borthwick, L. J. and Ross, I. S. (1979) *Lancet,* **1,** 924.
9. Steel, J. M., Cramb, R. and Duncan, L. J. P. (1980) *Practitioner,* **224,** 651.
10. Strickland, M. H. and Wales, J. K. (1982) ibid., **226,** 271.
11. Webb, D. J., Lovesay, J. M., Ellis, A. and Knight, A. H. (1980) *British Medical Journal,* **1,** 362.

Britannia Rules . . . ?

'London, the Epitome or Breviary of all Britain, the seat of the British Empire . . .'—these words from Camden's *Britannia* surely include an early, if not the earliest use of the title 'the British Empire'. However that may be, one might be justified in imagining, if not hoping, that with the College now in the London Borough of Camden and hard by Camden Town the latter owed its name to William Camden (1551-1623) who first published his famous book in 1586. There is nothing in the text about Camden Town, or for that matter Kentish Town, although the latter appears on the map of Middlesex. Instead, its name has a more exalted origin, being derived from Charles Pratt, who was created Earl of Camden of Camden Place, Kent, in 1765. The Earl, who had become Lord Chancellor and a freeman of the City of London and also of the Barber-Surgeons of Dublin, had married a daughter of Nicholas Jeffreys, and through him obtained possession of the manor of Kentish Town, part of which he began to let for building in 1791.

William Camden's closest local association is with Westminster. After being a pupil at Christ's Hospital he went to St Paul's School and then to Christ Church, Oxford. The son of a painter who came from Lichfield, Camden became second master at Westminster School, where Ben Jonson was a pupil, in 1575 and headmaster in 1597. When he died he was buried in Westminster Abbey. Although Camden Town does not owe its name to him, the society which was founded in 1838 for the purpose of publishing documents relating to the early literature and history of the British Empire was appropriately called the Camden Society.

When Camden left Oxford in 1571 and returned to London without regular employment, he began to collect material for his most famous work; in this he was urged on by Abraham Ortelius, the eminent cartographer, who had published his first atlas the year before. He tells us later: 'I have looked into most libraries, registers and memorials of churches, cities and corporations . . . I have poored upon many an old Rowle.' His book, which was to be mainly topographical, was the first to show, even in a rudimentary sense, the need to evaluate sources; 'upon fables I have in no wise relied, and that I might not digresse extravagantly, I have had often recourse to the title of my booke (as Plinie adviseth) and eftsoones demanded of myselfe why I took penne in hand.'

Written in Latin, the *Britannia* had passed through six editions by 1607, and by that time was much enlarged. Three years later, and under Camden's direction, the first English translation appeared. This was the work of Philemon Holland (1552-1637), a doctor of medicine and master of the free school at Coventry. He had already published translations of Livy, Plutarch, and Pliny's *Natural history* among others, which were distinguished for their vivid, familiar and somewhat ornamented English. He says of the maps, which are reduced versions of those of Christopher Saxton and John Norden, 'most skilful chorographers,' that they 'doe allure the eies by pleasant portraiture, and are the best directions in Geographicall studies, especially when the light of learning is adjoining to the speechlesse delineations.'

According to Camden, Britain is 'the most famous island without comparison of the whole world' and 'there

continued on page 212