A Comparison of Accuracy and Estimated Cost of Methods for Home Blood Glucose Monitoring

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Venous serum glucose concentrations determined by a laboratory hexokinase technique were compared over a wide range of glucose concentrations with concentrations of capillary blood glucose determined by three reflectance meter techniques currently available in the United States (Eyetone and Dextrometer, Ames Company; StatTek, Bio-Dynamics BMC) and by visual interpretation of reagent strips (Chemstrip bG, Bio-Dynamics BMC). The Chemstrip bG reagent strip was read by patients, nurses, and a physician. In all cases, there was an excellent correlation between laboratory serum glucose concentrations and reflectance meter blood glucose determinations ($r = 0.90-0.94$, $P < 0.0001$) or visual interpretation of Chemstrip bG ($r = 0.85-0.92$, $P < 0.0001$). Chemstrip bG appears to be the least expensive method of glucose measurement. This method offers additional advantages in not requiring a reflectance meter, which needs frequent recalibration and other ancillary equipment for blood glucose determination. DIABETES CARE 4: 396–403, MAY–JUNE 1981.

Measurement of capillary blood glucose levels by patients at home has been shown to improve blood glucose control in many diabetic subjects.[1–3] This technique has been shown to result in an improved outcome of pregnancy in diabetic subjects[1,4,5] and may be a means of reducing microvascular and other long-term complications of the disease.[6–8] Now that this approach has been shown to be feasible and has been advocated by some for large numbers of diabetic subjects,[3,9] an assessment of the accuracy, ease of use, and estimated cost of the various methods available for home blood glucose monitoring (HBGM) is important.

The availability of glucose-oxidase impregnated strips for rapid determination of blood glucose levels provides information to the patient, allowing rapid adjustments in therapy to control blood glucose levels.[3,10–12] The superiority of direct blood glucose monitoring over urine glucose determination is well recognized.[3,10–15] Advantages include greater accuracy of a quantitative method over a semiquantitative method, the preference of many patients to avoid handling urine, and the shorter time required than for a double-void urine collection. Most important, direct blood glucose monitoring provides quantitation of blood glucose levels below the renal threshold, which is increasingly important when the aim of therapy is to normalize blood glucose concentrations in an attempt to reduce complications of the diabetic state, such as complications during pregnancy, diabetic neuropathy, and microvascular disease.[7] In addition, the ability to immediately confirm hypoglycemia is very reassuring to patients and allows for rational treatment of hypoglycemic episodes. Finally, knowledge of blood sugar concentrations and the way in which these fluctuate in response to food and activity may raise the patients' consciousness as to the importance of compliance with a given regimen for normalizing blood glucose.

The present study was undertaken to evaluate the accuracy, convenience, and costs of three of the reagent strip/reflectance meter systems available in the United States and a recently marketed reagent strip not requiring the use of a reflectance meter. The potential patient population in whom HBGM may be of use is very large, and the choice of technique(s) may greatly influence the number of patients and types of circumstances in which HBGM can be applied, and the cost of such an intervention.

MATERIALS AND METHODS

Studies were performed on 16 unselected patients admitted to the University of Michigan Hospital Diabetes Center Unit over a period of 3 wk. Informed consent was obtained for the study.

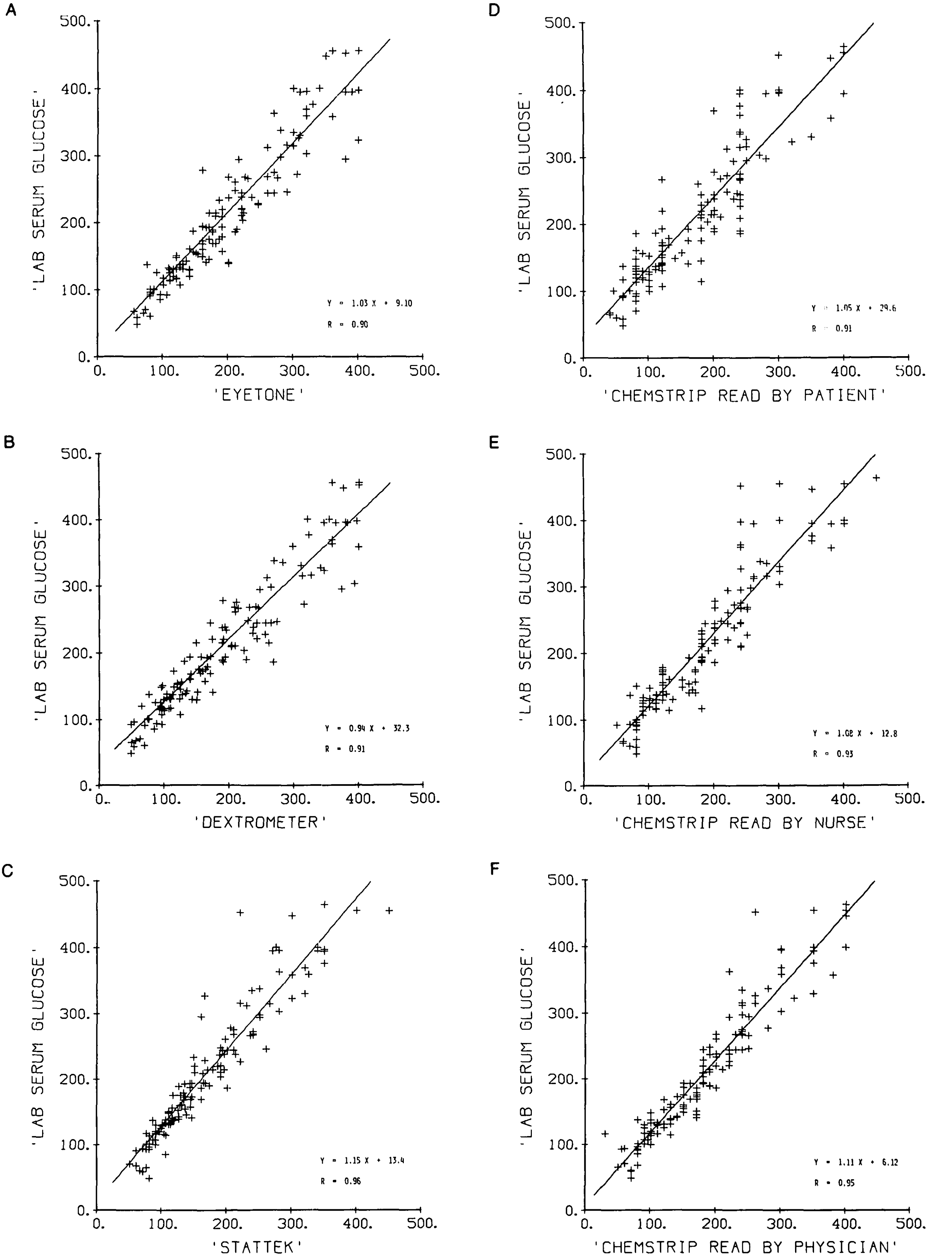

FIG. 1. Relationship of venous serum glucose concentration determined by hexokinase method (Lab Serum glucose) with capillary blood glucose by Eyetone (A), Dextrometer (B), StatTek (C) (A–C read by nurses and physician), Chemstrip bG read by patient (D), Chemstrip bG read by nurse (E), and Chemstrip bG read by physician (F).

Capillary blood glucose concentrations were measured by reflectance meter by a group of five trained nurses and one physician. The Chemstrip bG (Bio-Dynamics BMC, Indianapolis, Indiana) was read independently on each occasion by one nurse, a physician, and the patient.

Between 7:00 and 8:00 a.m. and 4:00 and 5:00 p.m., a venous blood sample was drawn and sent via routine hospital transport service for determination of serum glucose concentration by a hexokinase technique (Technicon SMAC)[16] within 2 h of venipuncture. Within 1 min of obtaining the venous blood sample, capillary blood was obtained by one or more finger pulp punctures using either a 26-gauge hypodermic needle or an Autolet lancet (Bio-Dynamics BMC). Four drops of freely flowing capillary blood were obtained and one was applied to each of the four reagent strips in random order: Chemstrip bG, StatTek Glucose (Bio-Dynamics BMC), and two Dextrostix (Ames Company, Elkhart, Indiana). To assess the utility of double-void urine glucose measurements, each patient voided and 15 min later a second urine sample was collected and analyzed by the patient for glucose concentration using TesTape (Eli Lilly and Company, Indianapolis, Indiana). Blood samples were obtained in the middle of the urine collection period.

The reagent strips were all exposed to capillary blood for exactly 1 min, after which the Chemstrip bG and StatTek glucose strips were wiped free of blood with three strokes of a cotton swab,and the Dextrostix washed with a jet of water and blotted dry in accordance with the manufacturer's instructions.

The reflectance meters studied were the StatTek (Bio-Dynamics BMC) used with the StatTek Glucose reagent strip; and Eyetone and Dextrometer (Ames Company) used with the Dextrostix reagent strips. In all cases, the manufacturer's instructions pertaining to warm-up, calibration, and operation of reflectometers were adhered to strictly. In the case of the StatTek, the dial provided is calibrated to measure serum or blood glucose. In these experiments the latter was used so that with all reflectometers, blood glucose was measured. The Chemstrip bG reagent strip was read against standards on its container (with interpolation when necessary) by a nurse, a physician, and the patient, independently and without knowledge of the other results.

To assess the manufacturer's statement that Chemstrip bG reagent strips could be stored and reread at a later time, 14 strips from 7 patients were stored in a cool, dark environment from 48 to 58 h and reread in random order by the same nurse, physician, and patient who performed the initial readings. In addition, 25 Chemstrips were prepared as described above and read by a physician in random order without identification on days 0, 1, 2, 7 and 14.

An additional 10 ml of heparinized blood was drawn from two groups of five patients on separate occasions. The blood glucose concentration was measured ten times on each sample by each of the three reflectance meters and the Chemstrip bG as described above. The samples from the first group of five patients were measured by a nurse (K.H.) and those of the second group by a physician (B.S.). In each instance, the order of the samples and the method of determination were randomized.

Data were analyzed by means of standard techniques for correlation analysis: simple linear regression, analysis of variance, Student's *t* test for paired and unpaired samples, as well as Wilcoxon's rank-sum test, where appropriate.

RESULTS

The blood glucose concentrations determined by reflectance meters and Chemstrip bG are compared with serum glucose concentrations obtained by the hexokinase method and shown in Figures 1A–F and in Table 1. The coefficient of variation for the hexokinase method was 7.3% at 67.3 mg/dl, 2.3% at 286.5 mg/dl, and 3.9% at 496.4 mg/dl. In all instances, a highly significant linear association was observed between capillary blood glucose concentration and that obtained by the hexokinase method. Table 1 examines this relationship for the full range of blood glucose encountered (48–464 mg/dl), and also for the range most relevant in attempts to normalize blood glucose levels and to avoid hypoglycemia (48–250 mg/dl).

TABLE 1
Relationship of venous serum glucose and capillary blood glucose concentrations measured by various methods

	Range: 48–464 mg/dl (N = 132)			Range: 48–250 mg/dl (N = 93)		
Method	Intercept	Slope	Correlation coefficient	Intercept	Slope	Correlation coefficient
Eyetone†	9.1	1.03	0.90*	21.2	0.89	0.91*
Dextrometer†	32.3	0.94	0.91*	45.6	0.78	0.90*
StatTek†	13.4	1.15	0.94*	16.7	1.08	0.92*
Chemstrip read by patient	29.6	1.05	0.91*	56.0	0.76	0.85*
Chemstrip read by nurse	12.8	1.08	0.93*	31.9	0.89	0.89*
Chemstrip read by physician	6.1	1.11	0.95*	22.4	0.95	0.92*

* All correlations are statistically significant, $P < 0.0001$.
† Determinations by a physician or nurse.

Except for the StatTek reflectance meter, all of the capillary techniques tended to underestimate glucose concentrations in the range 48–250 mg/dl. In all capillary methods, extrapolation of the regression line to the vertical axis showed a point of intersection above zero, indicating a potential to underestimate glucose concentrations at low levels.

In the case of the patients', and to a lesser extent the nurses', interpretations of the Chemstrip bG (Figures 1D and E), there is some clustering of readings at 80, 120, 180, and 240 mg/dl, indicating a preference for the standards displayed on the container, despite instructions to interpolate values when necessary. Despite this there were no significant differences in accuracy of readings by different observers.

The relationship between hexokinase determined serum glucose concentration and spot urine glucose is shown in Figure 2. The great variability of serum glucose concentrations at each urine glucose level demonstrates the very wide range of apparent renal threshold for glucose and the possible influence of failure of complete double-voiding or rapid fluctuaions in blood glucose levels. The correlation coefficient between serum and urine glucose concentrations (0.74) although highly significant, was less than that for serum glucose and capillary blood glucose determined by any of the HBGM methods (0.90–0.95).

When Chemstrip bG was read after a period of storage, a small but significant decrease (6.8%–10.1%) in the blood glucose concentration was noted by all observers at the time of the second reading (see Table 2). When read by a physician five times over a 14-day period, the decrease appeared to occur during the first 2 days and blood glucose concentrations remained constant thereafter (Figure 3).

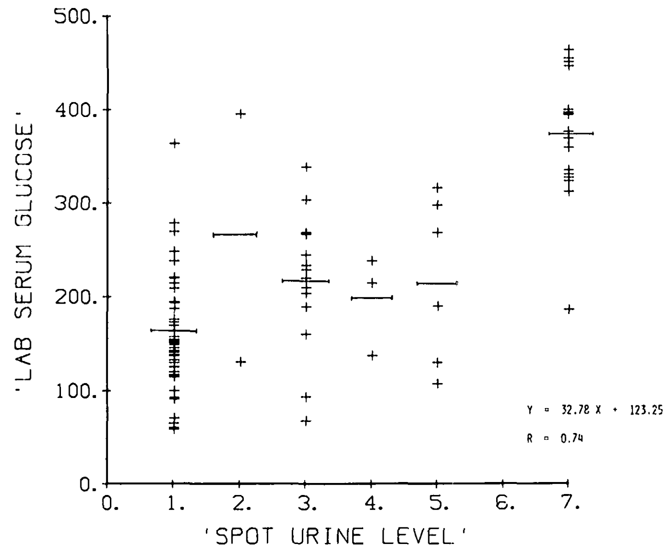

FIG. 2. Relationship of venous serum glucose concentration determined by hexokinase method (laboratory serum glucose) with urine glucose level (TesTape). Spot urine levels: 1 = none, 2 = trace, 3 = 0.10%, 4 = 0.25%, 5 = 0.50%, 6 = 1.00%, and 7 = 2.00%.

TABLE 2

Chemstrip-determined capillary blood glucose levels read 48–58 h apart

	Day 0 means (range) (mg/dl)	Mean difference Day 0–day 2 (mg/dl) ± SE	% Difference	P*
Lab venous (mg/dl)	215.8 (60–464)	—	—	—
Interpreter:				
Patient	181.4 (40–400)	−18.6 ± 4.7	−10.1%	<0.01
Nurse	177.9 (50–400)	−12.1 ± 4.6	− 6.8%	<0.02
Physician	193.9 (55–400)	−18.9 ± 5.3	− 9.7%	<0.002

* Wilcoxon's rank-sum test indicates significant difference between day 0 and day 2.

The results of repeated determination of blood glucose by the four reagent strip techniques are shown in Tables 3 and 4. The mean coefficient of variation for techniques when performed by a nurse using reflectance meters was 8.9%–11.3%, and that of Chemstrip bG 17.8%, (Table 3). When performed by a physician using reflectance meters it was 6.7%–9.0% and that for Chemstrip bG was 11.6% (Table 4). The large difference between one serum glucose concentration (188 mg/dl) and capillary blood glucose concentration measured by a nurse using Eyetone and Dextrometer reflectance meters is unexplained, especially as such a difference was not observed at other serum glucose levels (Table 3).

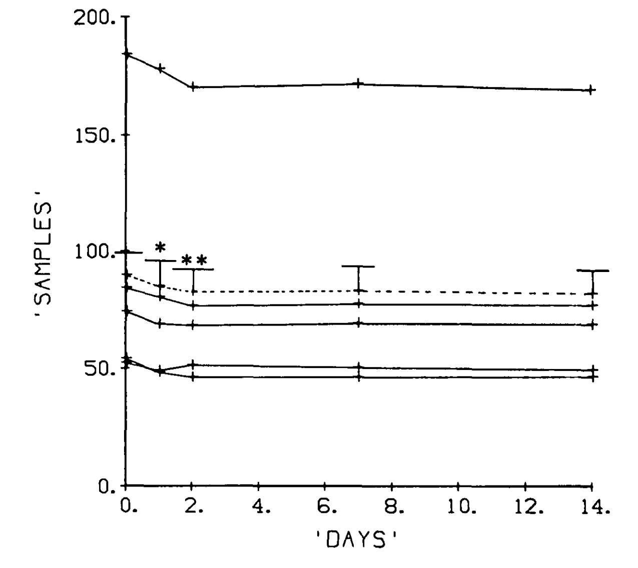

*FIG. 3. Reproductibility of blood glucose concentratin determined by Chemstrip bG initially and after storage. Unbroken lines represent mean reading for 5 strips at 5 blood glucose concentrations. Broken line represents mean values for the 5 blood glucose concentrations. The standard deviation is indicated only on the overall mean for clarity. *Day 1 significantly different from day 0, P < 0.001; ** day 2 significantly different from day 1, P < 0.01 (Student's t test). No further significant decreases occurred over the remaining measurements.*

TABLE 3
Variation of capillary blood glucose levels measured by a nurse using four methods at five glucose levels

Venous serum glucose level (mg/dl)	Eyetone Mean ± SD (N = 10)	CV*	Mean Δ	Dextrometer Mean ± SD (N = 10)	CV	Mean Δ	StatTek Mean ± SD (N = 10)	CV	Mean Δ	Chemstrip Mean ± SD (N = 10)	CV	Mean Δ
41	43.8 + 4.1	9.3	+ 2.8	43.6 ± 4.2	9.7	+ 2.4	47.2 ± 3.3†	6.9	+6.2	39.0 ± 3.2	8.1	− 2.0
62	60.7 ± 10.8	17.8	− 1.3	48.2 ± 2.7†	5.5	−13.8	69.5 ± 15.6	22.1	+7.5	60.0 ± 18.9	31.6	− 2.0
94	67.5 ± 3.7†	4.5	−26.5	69.4 ± 8.2†	11.8	−24.6	90.2 ± 13.5	15.0	−3.8	78.9 ± 15.5†	19.9	−15.1
188	133.2 ± 16.5†	12.4	−54.8	133.4 ± 11.6†	8.7	−54.6	180.5 ± 7.5†	4.1	−7.5	199.2 ± 25.6	12.9	+11.2
686	> 400.0	—	—	> 399	—	—	> 350	—	—	760.0 ± 126.5	16.5	+74.0
	Mean CV = 11.3			Mean CV = 8.9			Mean CV = 12.0			Mean CV = 17.8		

* Coefficient of variation (%).
† Significantly different from serum glucose concentration, $P < 0.05$ (Student's *t* test).

DISCUSSION

Home blood glucose monitoring with delayed analysis of glucose concentrations was initially performed on blood samples collected onto filter paper or into capillary tubes.[17,18] The development of glucose-oxidase impregnated reagent strips permitted rough estimation of blood glucose concentration, but it required the development of reflectance meters to permit more accurate quantitative use of reagent strips.[19] There are now several reflectance meter/reagent strip combinations available. The Chemstrip bG represents an attempt to return to a reagent strip for determining blood glucose concentrations without the use of a reflectance meter.

In this study the performance of three reflectometer/reagent strip systems and Chemstrip bG when used by health care professionals was compared. In addition, the performance of Chemstrip bG when used by health care professionals was compared with results obtained by patients. It has been previously shown that patients using reflectance meters are able to achieve results similar to those obtained by health care professionals.[10–15] All four capillary blood glucose measurement techniques showed a highly significant correlation with serum glucose concentration as determined by a standard hexokinase technique. The performance of the reflectance meters was not significantly different from that previously reported.[3,10–15] The marked underestimation of glucose concentration with the Eyetone and Dextrometer by the nurse of a sample having a serum glucose of 188 mg/dl is not readily explained. Possible explanations include incorrect calibration, differences between batches of reagents, or errors in technique. In the case of the Chemstrip bG, results are in keeping with preliminary results obtained thus far.[20–24] Studies to date, with the exception of Walford et al.,[20] have used venous rather than capillary blood and have not studied patient performance. Whether the tendency of the 16 patients to show a preference for the standards, leading to clustering of their glucose measurements at 80, 120, 180, and 240 mg/dl despite instructions to interpolate values, can be overcome remains to be determined. More prolonged observations are needed on a larger number of patients outside the hospital, a problem that has not been addressed to date. Although all patients did not formally evaluate the three reflectance meters, several patients expressed a preference for an instrument that provides an unequivocal reading of blood glucose concentrations over a method requiring decision making in the matching of reagent strips to a set of standard colors. In addition, the use of an instrument with a large dig-

TABLE 4
Variation of capillary blood glucose levels measured by a physician using four methods at five glucose levels

Venous serum glucose level (mg/dl)	Eyetone Mean ± SD (N = 10)	CV*	Mean Δ	Dextrometer Mean ± SD (N = 10)	CV	Mean Δ	StatTek Mean ± SD (N = 10)	CV	Mean Δ	Chemstrip Mean ± SD (N = 10)	CV	Mean Δ
57	51.7 ± 3.2†	6.2	− 5.3	55.1 ± 5.1	9.3	− 1.9	53.3 ± 3.8†	7.1	− 3.7	49.0 ± 8.8†	17.9	− 8.0
68	65.3 ± 5.8	8.8	− 2.7	60.7 ± 6.2†	10.3	− 7.3	63.3 ± 5.5†	8.7	− 4.7	58.0 ± 9.2†	15.8	−10.0
88	81.0 ± 4.6†	5.7	− 7.0	84.6 ± 8.9	10.5	− 3.4	80.8 ± 4.1†	5.0	− 7.2	73.0 ± 6.7†	9.3	−15.0
108	99.2 ± 6.5†	6.6	− 8.8	102.2 ± 9.8	9.6	− 5.8	103.0 ± 8.2	8.0	− 5.0	89.0 ± 7.4†	8.3	−19.0
197	175.5 ± 10.7†	6.1	−21.5	184.2 ± 9.3†	5.1	−12.8	185.0 ± 10.0†	5.4	−12.0	182.5 ± 12.3†	6.8	−14.5
	Mean CV = 6.7			Mean CV = 9.0			Mean CV = 6.8			Mean CV = 11.6		

* Coefficient of variation (%).
† Significantly different from serum glucose concentration, $P < 0.05$ (Student's *t* test).

TABLE 5
Specifications of four potential methods for home blood glucose monitoring

Technique	Reflectance meter: Weight (including cable and transformer)	Reflectance meter: Dimensions (mm)	Reflectance meter: Power source	Reagents and additional apparatus	Calibration materials required	Effective range (mg/dl) (proposed by manufacturer)	Reflectance meter cost ($)	Reagent strip cost ($/100)	Cost ($)§ per glucose determination (excluding cost of reflectance meter)* (a) (b)
Dextrometer (Ames)	443 g	160 × 100 × 42	16V DC via transformer from 115–120 AC†	Dextrostix: 3 glucose standards; wash bottle; paper towel	3 glucose standards, 3 reagent strips	0–399	339.95	40.59	0.71 to 1.32
Eyetone (Ames)	1692 g	180 × 110 × 48	16V DC via transformer from 115–120 AC	Dextrostix: 1 glucose standard; 2 calibration strips; wash bottle; paper towel	2 Calibration strips; 1 glucose standard; 1 reagent strip	10–400	395.00	40.59	0.51 to 0.71
StatTek (Bio-Dynamics)	1.102 g	221 × 146 × 78	115–120 AC	StatTek: glucose; 1 glucose standard; cotton swabs	1 Glucose standard; 1 reagent strip	50–350 (350–800)‡	375.00	57.75	0.72 to 1.01
Chemstrip bG (Bio-Dynamics)	—	—	—	Chemstrip bG: cotton swabs	—	20–800	—	53.00	0.53

* Calculated on the basis of four blood glucose determinations per day and calibration once (a) or three times (b) per day (the latter would be required if reflectometer were to be taken to and from home to place of work).
† Rechargable battery power source available as option.
‡ Estimation by visual inspection.
§ Costs calculated on basis of retail price as of 8/1/80.

ital display of glucose concentrations may be advantageous in the case of patients with visual impairment. Thus, although the Chemstrip bG allows as accurate a measurement of glucose concentrations as reflectance meters when performed by professionals, certain patients may obtain better results using a reflectance meter. Nevertheless, the results of this study and those of Walford et al.[20] indicate that this single reagent strip technique may be useful for a large fraction of patients.

All techniques of HBGM were superior to urine glucose measurements, the major defect of which was the wide range of blood glucose concentrations at each level of glycosuria. Normalization of blood glucose concentrations can be difficult to obtain in patients without the risk of hypoglycemia when urine testing alone is used for monitoring, because of the "blind area" below the renal threshold.[25]

Some specifications for the four techniques of blood glucose determination are shown in Table 5. All techniques are limited by the maximum level for the method. In the case of Chemstrip bG, estimation of blood glucose was possible to as high as 800 mg/dl. Visual examination and comparison with standards may be performed for the range 350–800 mg/dl with the StatTek Glucose Strip (manufacturer's instructions), as the StatTek reflectance meter reads to a maximum of 350 mg/dl. The StatTek system also provides reagent strips and calibration dials to measure glucose concentrations in the range 0–150 mg/dl, but this was not evaluated in this study.

The Chemstrip bG reagent strip technique offers several advantages. It does not require a reflectance meter, a power source, or calibration (which itself requires reagents and additional reagent strips prior to use). Hence, the cost per blood glucose determination is reduced (see Table 5). This technique is thus especially suited to diabetic subjects working away from home, traveling, and during or after exercise. Finally, in cases where a short period of HBGM is desirable this may be the technique of choice.

The stability of colors on the Chemstrip bG over periods up to 2 wk makes it possible for patients' HBGM readings to be verified by a health professional.[26] The slight reduction in values obtained on rereading occurring within the first 2 days does not appear to be of clinical significance.

If normalization of blood glucose is a goal in diabetic management,[6,7,19] HBGM can be an important adjunct in approaching or achieving this goal.[3,10–15] The choice of optimal technique may vary for individual patients. This investigation has indicated that reagent strips not requiring the use of a reflectance meter provide a technique of HBGM similar in performance to those using reflectance meters. Reagent strips are cheaper and less inconvenient and, thus, may be a means of extending HBGM to a larger patient population than has heretofore been considered feasible.

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