Home Monitors of Blood Glucose: Comparison of Precision and Accuracy

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Home monitors of blood glucose (HMBGs) are gaining acceptance as part of the standard of care for ambulatory self-monitoring and treatment of diabetic patients. Currently there are several HMBGs marketed in the United States, each claiming reliability, accuracy, and "user friendliness," with most of these claims largely unsubstantiated. The objective of our study was to analyze and statistically compare the accuracy and precision of the HMBGs produced by the major competitors in this ever-expanding medical field. Accuracy of each monitor was studied by comparing the glucose value reported by each HMBG with that determined by a reference method (YSI 23A). Precision or reproducibility of results was performed by testing a single, known whole-blood glucose sample 20 times on each monitor. The precision of each device was tested on known low, normal, and elevated samples. Actual and absolute deviations from the reference standard demonstrate that the Accuchek bG and Glucoscan 2000 monitors provide relatively unbiased estimates of blood glucose, whereas the Glucokey, Glucochek II, Glucometer II, and Trendsmeter generally underestimate the true values. The Diascan and Accuchek II monitors, in a separate evaluation, demonstrated acceptable accuracy and precision. We conclude that the Accuchek bG and Glucoscan 2000 statistically are the most accurate and precise HMBGs. *Diabetes Care* 10:360–66, 1987

In the early 1970s, the development of home monitors of blood glucose (HMBGs) gave the diabetic patient a more reliable and accurate method of determining blood glucose at home. Since the introduction of the Dextrometer, the first of these HMBGs, technological advancements in reflectance photometry have led to the development of newer and what are claimed to be more reliable, more accurate, and "user-friendly" monitors (1–13). These improvements have led the American Diabetes Association to issue a position statement recommending the use of HMBGs for inpatient diabetic control (14). In addition, the widespread use of HMBGs by the American public has become so prevalent that the ADA, Centers for Disease Control, Food and Drug Administration, and NIH recently convened a Consensus Development Conference on self-monitoring of blood glucose 17–19 November 1986. This conference specifically addressed the areas of medical and technical issues, training procedures, and the general impact of self-monitoring of blood glucose (15).

In the United States, the diabetic patient has the choice of various blood glucose monitors. Each of these devices claims accuracy and reliability, and these claims have been investigated to a small extent, usually directly by the manufacturers of these monitors or indirectly through their financial support (16–19). Although previous studies of an unbiased nature have been performed (20), the objectives of our study were to analyze and compare the accuracy and precision of the currently available and highly promoted HMBGs in this ever-growing medical industry. Monitors and reagent strips for our study were donated by the manufacturers; however, no financial support or backing was permitted by the investigators.

MATERIALS AND METHODS

Subjects. Venous blood samples were drawn from 60 adult diabetic and nondiabetic volunteers to obtain a wide range of whole-blood glucose determinations. Samples were col-

TABLE 1
Home monitors of blood glucose

Monitor	Manufacturer	Reagent strip
Accuchek bG	Boehringer-Mannheim, Indianapolis, IN	Chemstrip bG
Accuchek II*	Boehringer-Mannheim	Chemstrip bG†
Diascan*	Home Diagnostics, Eatontown, NJ	Diascan strips
Glucochek II	Larken Industries, Lenexa, KS	Chemstrip bG
Glucokey	Ulster Scientific, Highland, NY	Chemstrip bG
Glucometer II	Ames, Miles Laboratories, Elkhart, IN	Glucostix
Glucoscan 2000	Lifescan, Mountain View, CA	Glucoscan strips
Trendsmeter	Orange Medical Instruments, Costa Mesa, CA	Trendstrip

*Tested separately after initial study.
†Strips specially formulated for use with Accuchek II.

lected in Vacutainer tubes containing EDTA and used immediately to test the HMBGs and for reference value determinations. Volunteers gave informed consent before donating blood.

Procedure. Monitors tested in this study are listed in Table 1. The objective of phase 1 of the study was accuracy evaluation. This was accomplished by testing each venous whole-blood sample in duplicate on each HMBG over a range of glucose concentrations. Testing of the monitors was done with disposable pipettes to apply blood samples to the test strips. Samples were immediately analyzed after venipuncture by both the meters and the reference method, the YSI 23A whole-blood glucose analyzer (YSI, Yellow Springs, OH). This analyzer was selected over serum glucose analyzers as the reference method because of its reliability and ability to analyze glucose concentrations with whole-blood samples. This technique eliminates the need for cumbersome and imprecise conversion factors required in converting serum glucose determinations to equivalent whole-blood glucose values as displayed by the HMBG. To eliminate multiple-user bias, all evaluations on one group of four monitors were performed by one investigator and all evaluations on the second group of four monitors by another investigator. Both investigators had extensive training and experience in the operational techniques of each monitor. One technician performed all tests on the YSI and recalibrated the analyzer after every seven samples. Sample analysis with the monitors was performed to manufacturer's specifications, and each monitor was cleaned per manufacturer's directions after the testing of every five duplicate samples.

Although many of the newer monitors are capable of reading blood glucose values of 0–10 mg/dl, several of the test monitors did not record a numeric value but rather displayed the word *low* or gave a similar alphabetic notation with blood glucose values <50 mg/dl. A similar alphabetic reading of *high* was given when the blood glucose value exceeded the capabilities of the monitor. When the reading for one monitor was too low or high to analyze and statistically compare, that entire sample was excluded from the study.

The objective of phase 2 of the study was to evaluate the reproducibility of results or precision of each HMBG. This was accomplished by testing a single, known whole-blood glucose sample 20 times on each monitor. The precision of each device was tested on a known low-glucose sample (<60 mg/dl), normal- to high normal-glucose sample (146 mg/dl), and high-glucose sample (>320 mg/dl).

Analysis of data. Data collected from each monitor during phase 1 of the study were analyzed for accuracy by the weighted least-squares method, which assumed a model of constant coefficient of variation (C.V.). The weighted least-squares analysis was utilized to emphasize the lower blood glucose values over the less clinically relevant high blood glucose determinations. The percent deviations from the reference YSI values were analyzed by robust one-way analysis of variance (ANOVA), with pairwise comparison by the Wilcoxon/Mann-Whitney test. Regression statistics were compared with their ideal values by assuming that deviations from the ideal divided by the SE of estimate are normally distributed. Because monitors may be very precise yet have a very inaccurate regression line, or conversely, may have a very accurate regression line but lack precision, the mean-square percent error was used as a measure of overall performance because it combines both types of error. In addition, absolute percent differences from the YSI were compared with the Friedman rank-sum procedure. The 5% level of significance was used. Phase 2 of the study compared the precision of the instruments with standard statistical methods of mean, SD, and C.V.

Initial monitors studied and evaluated included the Accuchek bG, Diascan, Glucochek II, Glucokey, Glucometer II, Glucoscan 2000, and Trendsmeter. At the time of the study, the Accuchek II had not been released for use in the U.S. In addition, the Diascan strips used in the initial study were recalled by the manufacturer due to calibration defects,

TABLE 2
Coefficients of variation and mean-square percent errors, determined from regression analysis, for eight home monitors of blood glucose

Monitor	Coefficient of variation	Mean-square percent error
Accuchek bG	6.89	7.62
Accuchek II	7.92	12.31
Diascan	5.56	23.49
Diascan (2nd evaluation)	10.51	13.04
Glucochek II	8.11	17.74
Glucokey	26.90	31.68
Glucometer II	10.80	12.97
Glucoscan 2000	6.17	6.18
Trendsmeter	6.33	17.33

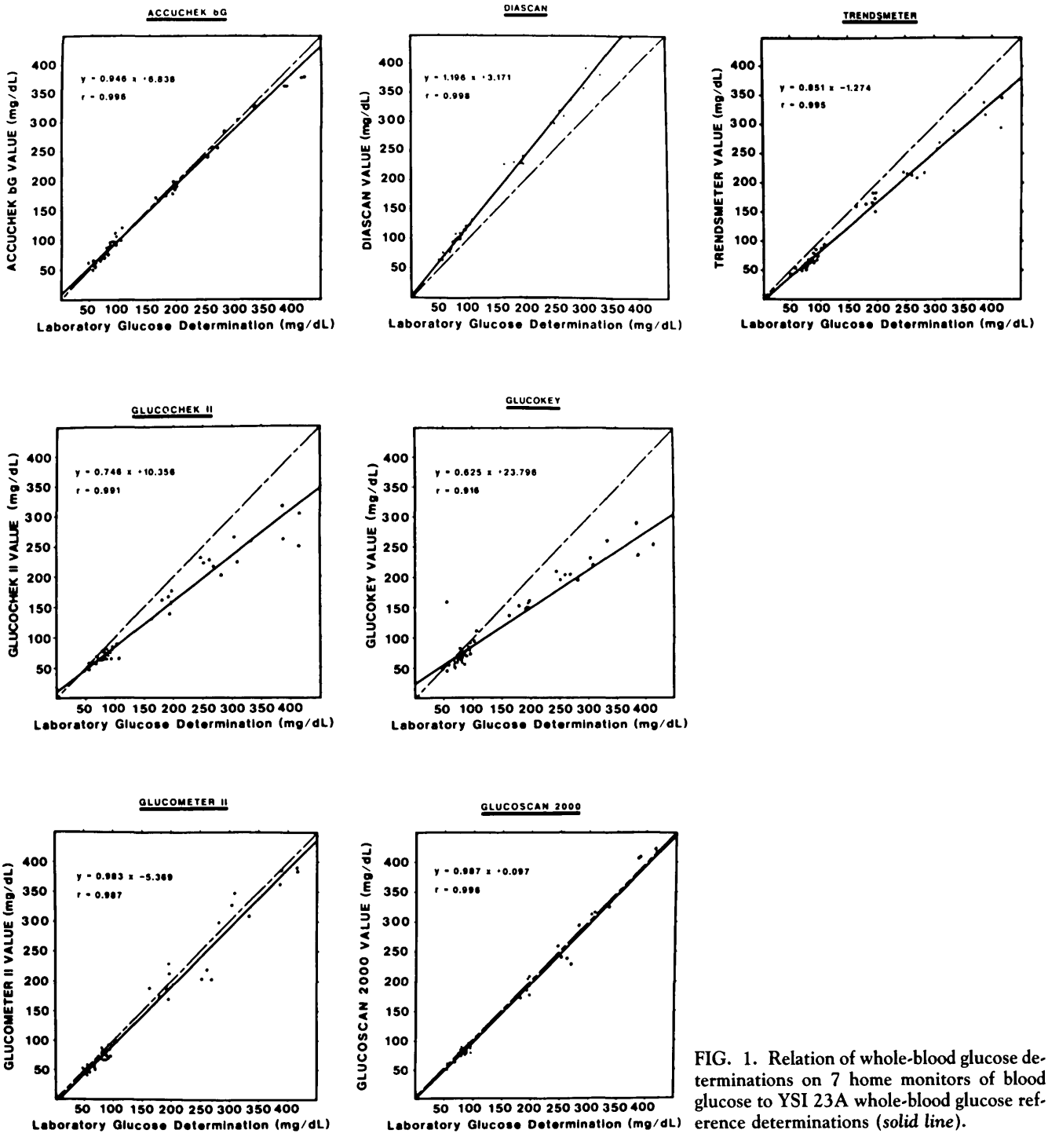

FIG. 1. Relation of whole-blood glucose determinations on 7 home monitors of blood glucose to YSI 23A whole-blood glucose reference determinations (*solid line*).

and the decision was made to reevaluate this meter with new strips. A separate evaluation of the Accuchek II and the Diascan was completed at a later date with the methods listed above on 34 venous blood samples. Although these data cannot be compared statistically with the original seven monitors studied, the regression analysis of the two meters was performed and precision data determined.

RESULTS

The accuracy data collected in this study include 56 determinations on each of seven HMBGs. Four subjects in the original 60 were excluded due to elevated hematocrits, which adversely affect the performance of these monitors. Scattergrams that display the readings of each of the seven moni-

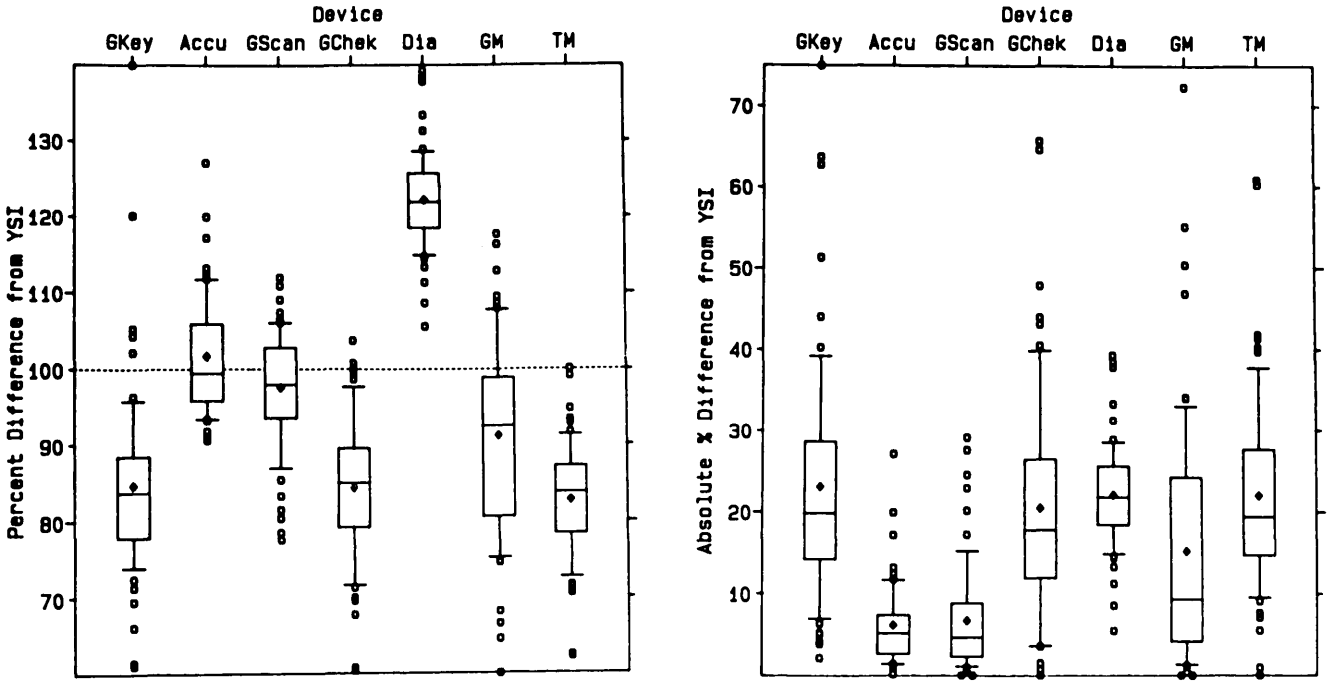

FIG. 2. Distribution of percent differences (*left*) and absolute percent differences (*right*) from YSI 23A reference method for Glucokey (GKey), Accuchek bG (Accu), Glucoscan 2000 (GScan), Glucochek II (GChek), Diascan (Dia), Glucometer II (GM), and Trendsmeter (TM). *Boxes* span 25–75 quartiles, with median *line*. *Upper* and *lower bars* indicate 90th and 10th percentiles. ♦, Means. Remaining data are plotted. $n = 56$.

toring devices with the YSI reference standard are included in Fig. 1. The 95% confidence intervals on the slopes of the regression lines fail to cover unity for every device except the Glucoscan 2000. Slopes for the Glucokey, Glucochek II, Diascan, and Trendsmeter are all substantially different from unity. Intercepts are very different from zero statistically for the Glucokey, Accuchek bG, and Glucochek II ($P < .05$).

Correlation coefficients were >.98 for all monitors tested except the Glucokey; however, the numbers are misleading for several of the devices because their regression slopes were far from unity. This accounts for the relatively small C.V.s for some devices (i.e., small deviations about the estimated regression lines) coupled with large mean-square percent errors, which is the better measure of device performance (Table 2).

Actual and absolute percent deviations of these meters from the YSI reference are presented in Fig. 2. The Accuchek bG and Glucoscan 2000 provide relatively unbiased estimates of blood glucose, whereas the Glucokey, Glucochek II, Glucometer II, and Trendsmeter generally underestimate the true values. The Diascan substantially overestimated true values. The Accuchek bG and Glucoscan 2000 have much smaller ranges and mean values than the other meters with very little statistical difference between the two ($P = .74$). The other meters all have much greater dispersion and larger absolute errors, and all are statistically different from Accuchek bG and Glucoscan 2000 ($P < .001$). Because of the limitations of many meters of not being able to read glucose values in the range 0–50 mg/dl, conclusions regarding accuracy and precision of these meters at that range cannot be drawn.

The absolute percent differences from the YSI reference standard were also compared with the Friedman rank-sum procedure. The Accuchek bG and Glucoscan 2000 were again found to be statistically different from the other meters, with the Friedman test yielding a χ^2 of 162.86 with 6 df ($P < .00001$).

The results of precision testing are presented in Table 3. The Accuchek bG and Glucoscan 2000 again were found to be superior to the other meters throughout the range of glucose concentrations by demonstrating lower C.V.s and SDs. At lower glucose concentrations, all monitors other than the Diascan and the Glucokey were found to be sufficiently precise, with C.V.s <5%. In the high-normal glucose range, the Diascan, Glucokey, and Glucochek II failed to demonstrate adequate precision, whereas the others again produced C.V.s <5%. Elevated glucose concentrations resulted in elevated C.V.s for the Diascan, Glucochek II, and Trendsmeter. The results of precision testing for the Accuchek II were 51.05 ± 1.73 (mean ± SD), C.V. 3.39, for low reference concentrations (50 mg/dl); 124.6 ± 3.97, C.V. 3.18, for medium reference concentrations (125 mg/dl); and 210.6 ± 4.15, C.V. 1.97, for high reference concentrations (215 mg/dl). These statistical values tend to suggest acceptable precision for the Accuchek II.

Regression analysis of the Accuchek II HMBG and analysis

TABLE 3
Statistical analysis of precision data

Reference value*	Monitor						
	Accuchek bG	Diascan	Glucochek II	Glucokey	Glucometer	Glucoscan	Trendsmeter
Low (48–53 mg/dl)							
Mean	48.60	57.40	47.90	56.05	60.10	52.20	43.50
SD	1.67	3.49	1.71	5.97	2.61	1.36	2.12
C.V. (%)	3.43	6.08	3.57	10.65	4.34	2.34	4.87
Medium (146 mg/dl)							
Mean	141.90	158.35	120.80	123.85	135.80	136.40	142.00
SD	3.77	11.17	13.72	9.09	5.33	5.95	5.72
C.V. (%)	2.66	7.05	11.36	7.34	3.92	4.36	4.03
High (321–383 mg/dl)							
Mean	334.75	344.30	273.35	224.00	343.40	383.75	284.40
SD	7.48	37.06	30.77	10.22	16.32	12.83	17.39
C.V. (%)	2.23	10.76	11.26	4.56	4.75	3.34	6.11

C.V., coefficient of variation. $n = 20$.
*YSI determinations at beginning and end of precision testing (range difference due to glycolysis during testing); no change was observed for medium reference value.

of the reevaluation of the Diascan meter with new Diascan strips are included in Fig. 3. Inasmuch as these two meters were tested with a different population of whole-blood glucose samples, statistical comparison with the original study meters is difficult at best. However, the regression equations and correlation coefficients obtained for these meters tend to suggest acceptable precision and accuracy characteristics for these monitors.

DISCUSSION

Acceptable monitor performance is a combination of accuracy and precision. In our study, greatest accuracy is implied when monitor results are regressed on the laboratory reference and a slope and intercept of the regression line are produced that are close to their ideal values of unity and zero, respectively. Precision means that variability about this regression line is small. Monitors, however, may be very precise (i.e., have a small C.V.) about a very inaccurate regression line, or conversely, may have a very accurate regression line but lack precision. For example, a marksman who consistently places all of his shots within a 1-inch-diam circle is precise; however, one would not want him to attempt to shoot an apple off one's head if he always placed his 1-inch cluster of shots 3 inches below the bull's-eye. Although some monitors demonstrate adequate regression equations and most monitors demonstrate impressive correlation coefficients, only the Accuchek bG and Glucoscan 2000 adequately combine these characteristics. The later evaluation of the Accuchek II suggests acceptable accuracy and precision for this monitor as well.

Accuracy and precision performance were also evaluated by the comparison of the mean-square percent error of each monitor with its respective C.V. Best performance is obtained when the mean-square percent error is not much larger than the C.V. This criterion was met by the Glucoscan 2000, Accuchek bG, Glucometer II, and Glucokey, although precision is poor for the latter two, especially Glucokey. Glucochek II and Trendsmeter possess rather good precision (small C.V.) about badly biased regression lines. The initial Diascan evaluation suffered from both poor precision and inaccuracy; however, when reevaluated with new test strips, this monitor performed substantially better. Additionally, Accuchek II, evaluated independently of the other monitors, also demonstrated only a small difference between the mean-square percent error and the C.V. (Table 2).

An overall analysis of the data permits the monitors to be placed into distinctive groups. The Accuchek bG and Glucoscan 2000 can be categorized together based on their good performance characteristics with mean-square errors of ~8% and little difference between them. The Accuchek II, in its separate evaluation, demonstrated a moderately elevated mean-square percent error; however, with this exception it would fit appropriately into the Accuchek bG and Glucoscan 2000 group. A second group of monitors, including the Glucochek II, Diascan, and Trendsmeter, all have relatively small C.V.s about regression slopes that are substantially different than ideal (unity) and hence, large mean-square percent errors and large absolute percent errors. The Glucometer and the reevaluated Diascan had regression slopes near unity and modest median mean-square percent errors, but substantial C.V.s about their regression lines. Unfortunately, the Glucokey displayed inferior performance characteristics as assessed by a number of parameters.

The Glucokey HMBG, distributed in the U.S. by Ulster

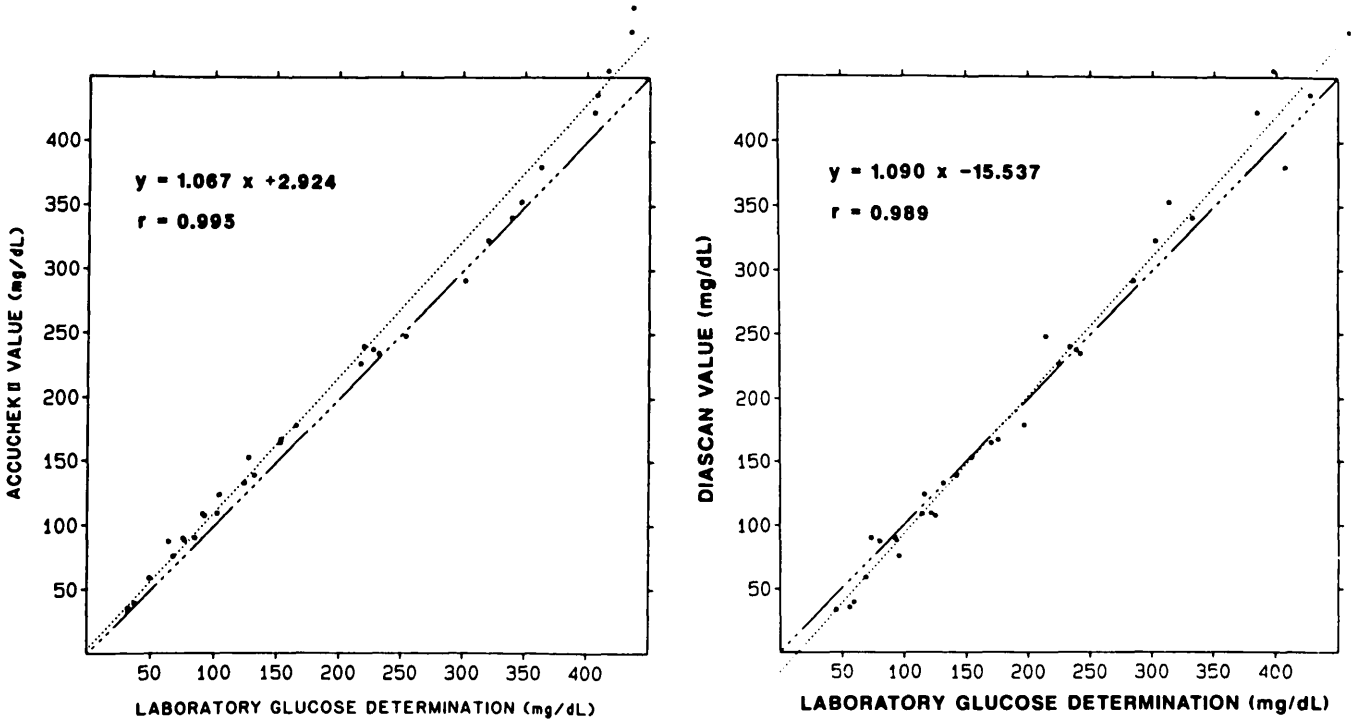

FIG. 3. Relation of Accuchek II (*left*) and Diascan (2nd evaluation) (*right*) whole-blood glucose determinations to YSI 23A whole-blood glucose reference determinations (*dotted line*).

Scientific and manufactured by Clinitron of Great Britain, is no longer available to consumers in this country. However, a similar monitor manufactured by Clinitron, the Diagem, is available in the U.S. and distributed by a different company. It is our understanding that the Diagem is identical to the Glucokey except for the nameplate on the monitor.

CONCLUSIONS

The data presented in our study represent the statistical comparison of values obtained on a single representative monitor from each major manufacturer that distributes these devices in the U.S. Although the manufacturers of these devices will state that the variance between the monitors they produce is minor, we recognize the potential for having obtained a faulty meter for use in our research. Indeed, a problem with faulty reagent strips did occur in this study. Considering the importance of accuracy and precision in the HMBG concentrations, the chances of obtaining a defective medical device should be negligible. We must, however, emphasize that this study is an independent comparison of the precision and accuracy of only one representative sample of each company's HMBG.

In addition, we evaluated meter performance rather than user technique. Pipetted blood samples, as used in this study, eliminated an element of error produced by the finger-stick method. Precision and accuracy of HMBGs, tested in the hands of the diabetic consumer, should be the objectives of further investigations.

Although this study evaluates the statistical rather than the clinical significance of meter accuracy and precision, HMBGs, for the most part, are clinically accurate in the hands of well-trained individuals. Each meter has its own advantages and disadvantages regardless of precision and accuracy. Cost, portability, and user friendliness all play a role in the selection of whole-blood glucose monitors. The choice of an HMBG should be made by combining the statistical data presented in studies such as this with the needs and desires of the diabetic consumer.

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