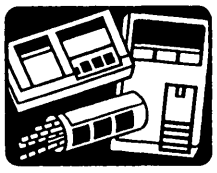
Technical Articles



Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose

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Although the scientific literature contains numerous reports of the statistical accuracy of systems for self-monitoring of blood glucose (SMBG), most of these studies determine accuracy in ways that may not be clinically useful. We have developed an error grid analysis (EGA), which describes the clinical accuracy of SMBG systems over the entire range of blood glucose values, taking into account *1*) the absolute value of the system-generated glucose value, *2*) the absolute value of the reference blood glucose value, *3*) the relative difference between these two values, and *4*) the clinical significance of this difference. The EGA of accuracy of five different reflectance meters (Eyetone, Dextrometer, Glucometer I, Glucometer II, Memory Glucometer II), a visually interpretable glucose reagent strip (Glucostix), and filter-paper spot glucose determinations is presented. In addition, reanalyses of a laboratory comparison of three reflectance meters (Accucheck II, Glucometer II, Glucoscan 9000) and of two previously published studies comparing the accuracy of five different reflectance meters with EGA is described. EGA provides the practitioner and the researcher with a clinically meaningful method for evaluating the accuracy of blood glucose values generated with various monitoring systems and for analyzing the clinical implications of previously published data. *Diabetes Care* 10:622–28, 1987

Self-monitoring of blood glucose (SMBG) has become an important tool in the management of patients with diabetes mellitus (1,2). Numerous systems have been developed and upgraded in an effort to facilitate the ease and accuracy of patient-generated glucose values. Extensive published research attests to the accuracy of these systems both in the laboratory and during observed patient use (3–38). Most of these reports, however, determine accuracy in ways that may not be clinically useful and therefore make it difficult to evaluate the clinical significance of a particular product or method. Whether a particular system, regardless of cost or ease of use, offers a distinct clinical advantage over another system cannot be easily evaluated with the statistical methodology (correlation coefficients and linear regression, percent deviation, mean differences) reported by most investigators.

Specific problems exist with each of these statistical methods. Correlation coefficients describe the linear relationship of two sets of data. The *r* value, however, can be close to unity for very large sets of data when individual data points differ by large amounts. In addition, correlation coefficients that evaluate the entire range of blood glucose values may misrepresent the true relationship between subsets of data. For example, Pohl et al. (36) report a correlation coefficient of .91 for a comparison of 2145 blood glucose determinations over the reference glucose range of 10–400 mg/dl, only .49 when the actual blood glucose is <70 mg/dl, and .60 when the actual blood glucose is >300 mg/dl. Linear regression equations determine the slope of the best-fitting line that relates two data sets, but like correlation coefficients, a slope that approaches unity cannot always predict the relationship between two specific data points.

Percent deviation may be a more clinically useful measurement but only if there is a consistent percent difference that is clinically meaningful over the entire range of data being reported. This is not true for data comparing glucose-monitoring systems with standard reference methods. For example, a 100% deviation from an actual blood glucose of 20 mg/dl should not result in inappropriate therapy for hypoglycemia, yet a 100% deviation from an actual blood glu-

TABLE 1
Summary of methodology of self-monitoring of blood glucose system accuracy analyses

Monitoring system	Reference system	Blood sample	Readers	Statistical analysis	Refs.
Eyetone	O,Y,B,H	C,V	L,P	L,C,M,P,C.V.	3,6–9,11–14,36
Dextrometer	H,B,O	C,V	L,P,N,D	L,C,M,P	12,13,16,19,36
Dextrostix	O	V,C	L	L,C,C.V.	3,11,14
Glucometer	B,Y	V,C	L,P,N	C,M,L,C.V.,P	13,18,19,21,22,36,37
Chemstrips bG	B,O,H,Y	C,V	P,N,D,L	P,N,C,L,C.V.,M	10–13,15–17,19,20,22–24, 26,28,31,33–35,38
Visidex	B,Y,H	V	L	C,L,M	22–26,31,35
Visidex II	B	V	L	C,L,M	31
Accucheck	O,B,H	V	L,B	C,L,M,C.V.	14,22,27,30,32,37
Glucoscan I	Y,B	V	N	L,C,P,C.V.	21,29,37
Hypocount	B,Y	V	L,N	L,C,M,P	13,21
Stat Tek	Y,H,B,O	C,V	L,C,N,P	L,C,M,P	7,12,13,19
Glucocheck	Y,B,O	V	L	L,C,M,C.V.	7,8,13,14,37

Reference systems: B, Beckman glucose analyzer; Y, YSI whole-blood glucose analyzer; H, hexokinase determination; O, other laboratory analyzer. Blood sample source: C, capillary; V, venous. Readers: L, lab personnel; P, patients; D, doctors; N, nurse; B, blind. Statistical analysis: L, linear regression; C, correlation coefficient; P, percent deviation; C.V., coefficient of variation; M, mean difference.

cose of 150 mg/dl would result in an inappropriate treatment decision. The same arguments hold for mean differences between two sets of data.

A recently reported "precision index" appears to provide a useful clinical method for evaluating accuracy (39), but on closer examination this system has major shortcomings. A 30 vs. 60 mg/dl comparison is treated the same as a 300 vs. 600 mg/dl comparison, yet the clinical significance of the two errors is quite different. In addition, the precision index is inflated by overestimates of blood glucose. With this method, a 100-mg/dl overestimate of a blood glucose value of 40 mg/dl would result in a precision index of 1.5 (>0.8 = good, <0.7 = bad), whereas a similar overestimate of a blood glucose of 300 mg/dl would produce a value of 0.33. Underestimates, regardless of their magnitude, can never result in a precision index value of ≥1.0.

Table 1 summarizes the methodologies reported in 34 journal articles pertaining to the evaluation of SMBG systems. These publications, dating back to 1978, report the accuracy of 12 different SMBG systems and include 25 combinations of comparisons of these systems. These studies were conducted with nurses, lab technicians, physicians, trained and untrained volunteers, children, adults, and blind patients as readers. Venous blood, capillary blood, and plasma were tested, and four different reference systems were used for determination of accuracy. Each study included different ranges of reference blood glucose values and different sample sizes. Fifty-six linear regression equations and correlation coefficients were presented. Clearly, selecting an appropriate study with which to compare personal clinical experiences or patient-generated blood glucose data presents many difficulties.

What the practitioner needs is an evaluation that describes accuracy over the entire range of blood glucose values and evaluates the clinical and statistical significance of a particular system's accuracy. Such an accuracy quantification procedure should take into account the absolute value of the patient-generated glucose measurement, the absolute value of the reference blood glucose value, the relative difference between these two values, and the clinical significance of this difference. In addition, this evaluation procedure should be readily adaptable to published reports of the accuracy of various monitoring systems regardless of the study design and be capable of describing the clinical accuracy of new and diverse methods of monitoring, such as patient estimations, filter-spot analysis, memory meters, or capillary tube collections.

METHODS

We have recently developed a system for the evaluation of the clinical implications of patient-generated blood glucose values, which takes into account the four factors listed above (40; Fig. 1). The error grid analysis (EGA) defines the *x*-axis as the reference blood glucose and the *y*-axis as the value generated by the monitoring system. The diagonal represents perfect agreement between the two, with data points above and below the diagonal representing overestimates and underestimates, respectively. This method is based on assumptions that reflect clinical practices within our medical center: *1*) the target blood glucose range or the range of glucose values that we teach our patients to attempt to attain and maintain is between 70 and 180 mg/dl, *2*) patients will attempt to correct blood glucose readings that are above or below the target range but not those readings that are within the target range, *3*) corrective treatment by the patient is inappropriate if such treatment results in blood glucose values outside of the target range, and *4*) failure to treat blood glucose values <70 or >240 mg/dl is inappropriate. (A value of 240 rather than 180 mg/dl is arbitrarily used in the last

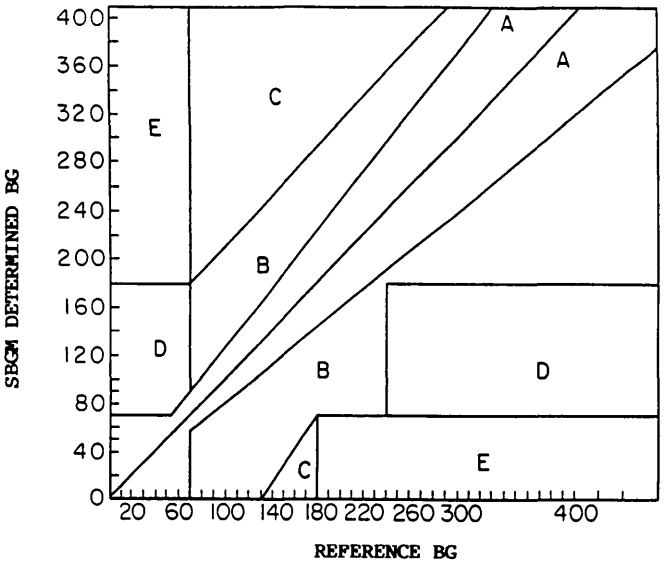

FIG. 1. Error grid analysis for evaluation of clinical implications of patient-generated blood glucose values. SBGM, self-monitoring of blood glucose; BG, blood glucose.

assumption, because lowering a blood glucose value slightly greater than the target might frequently result in a blood glucose value outside of the target zone.)

Based on these assumptions the grid is divided into five zones of varying degrees of accuracy and inaccuracy of glucose estimations. Zone A represents glucose values that deviate from the reference by no more than 20% or are in the hypoglycemic range (<70 mg/dl) when the reference is also <70 mg/dl. Values falling within this range are clinically accurate in that they would lead to clinically correct treatment decisions. Upper and lower zone B represents values that deviate from the reference by >20% but would lead to benign or no treatment based on our asssumptions. Zone C values would result in overcorrecting acceptable blood glucose levels; such treatment might cause the actual blood glucose to fall below 70 mg/dl or rise above 180 mg/dl. Zone D represents "dangerous failure to detect and treat" errors. Actual glucose values are outside of the target range, but patient-generated values are within the target range. Zone E is an "erroneous treatment" zone. Patient-generated values within this zone are opposite to the reference values, and corresponding treatment decisions would therefore be opposite to that called for. In summary, values in zones A and B are clinically acceptable, whereas values in zones C, D, and E are potentially dangerous and therefore are clinically significant errors.

The utility of this system for evaluating the clinical relevance and accuracy of various systems for monitoring of blood glucose has been examined. We have analyzed the following blood glucose data sets: *1*) values obtained by hospitalized patients with either Eyetone, Dextrometer, or Glucometer I (Ames, Miles, Elkhart, IN) reflectance meters compared with simultaneous plasma glucose values determined with a Beckman glucose analyzer (Fullerton, CA); *2*) values obtained by laboratory personnel from samples collected from people with diabetes, with the Glucometer II (Miles) compared with whole-blood glucose values measured with a YSI glucose analyzer (Yellow Springs, OH); *3*) values obtained by laboratory personnel from samples collected from people with diabetes, with Glucostix (Miles) compared with whole-blood glucose values measured with a YSI glucose analyzer; *4*) values obtained by laboratory personnel from samples collected from people with diabetes and by patients from their own blood, with the Memory Glucometer II (Miles) compared with whole-blood glucose values measured with a YSI glucose analyzer or simultaneously obtained plasma glucose values with a Beckman glucose analyzer, respectively; and *5*) values obtained by laboratory personnel from samples collected from people with diabetes, with a dried filter-paper blood-spot technique compared with simultaneous plasma glucose values determined with a Technicon RA-1000 autoanalyzer (Tarrytown, NY). In addition, we present an analysis of a comparison of three available reflectance meters performed by the University of Virginia Clinical Chemistry Laboratories and a reanalysis of data previously published by other groups of investigators.

RESULTS

EGAs of 2145 patient-generated data sets utilizing Eyetone, Dextrometer, and Glucometer I reflectance meters compared with a Beckman glucose analyzer are shown in Table 2. The correlation coefficient for these data is .91, and the linear regression equation is $y = .92x + 20.09$. This information alone does not permit the reader to evaluate the clinical accuracy of these patients' glucose determinations because, as stated earlier, the correlation coefficients in different blood glucose ranges are vastly different (36). However, EGA results confirm that 98% of the patient-generated values are clinically correct or acceptable and that 3 times out of 1000 readings, patients measured a high blood glucose (>180 mg/dl) when their actual blood glucose value was in the hypoglycemic range (<70 mg/dl). Similarly, 752 data sets generated with the Glucometer II compared with YSI glucose analyzer readings result in a correlation coefficient of .97 and

TABLE 2
Error grid analysis of accuracy of reflectance meter blood glucose readings

Zone	Eyetone, Dextrometer, Glucometer I* (n = 2145)	Glucometer II† (n = 752)
A	90.4	91.3
B	7.6	7.9
C	0.1	0
D	1.6	0.8
E	0.3	0

Values are percentages.
*$r = .91$; $y = 0.92x + 20.09$.
†$r = .97$; $y = 0.95x + 2.86$.

a regression equation of $y = .95x + 2.86$ (W.L.C., D. Becker, D.C., J. Santiago, N. White, J. Betschart, K. Eckerode, L. Levandoski, E. Prusinski, L. Simineiro, A. Snyder, A. Tideman, and T. Yaeger, unpublished data). EGA results show that 99.2% of these values would be clinically acceptable (zones A and B), whereas 0.8% represent failure to detect high or low blood glucose levels (zone D).

Another important use of the EGA is to evaluate the accuracy of visually interpreted reagent strips, the results of which are too imprecise for statistical analysis. Table 3 includes data sets comparing Glucostix with YSI glucose values (W.L.C. et al., unpublished data) and shows this strip is capable of producing a high percentage of accurate data: 96.1% zones A and B. There are, however, nearly five times as many clinically unacceptable results with Glucostix (3.9% zones C–E) than with the Glucometer II reflectance meter (0.8% zone D).

Table 4 shows data obtained at our center with the Memory Glucometer II. The first column displays the comparisons obtained with this device in the laboratory, and the second column displays the results of patient-obtained data. Although the clinically acceptable (zones A and B) results are similar for both groups of readers, more zone A readings are obtained by laboratory personnel (83%) than by patients (73.9%). It remains to be determined whether this new system will prove to be an acceptable method for patient SMBG.

Interestingly, if all errors (zones C–E) generated by the seven systems evaluated above (Eyetone, Dextrometer, Glucometer I, Glucometer II, Memory Glucometer II, Glucostix) are considered, 89% fall in zone D and are failures to detect and treat blood glucose values that are actually <70 or >240 mg/dl. Five percent of errors would result in overcorrecting acceptable blood glucose levels (zone C), and 6% of errors would lead patients to treat themselves in the opposite manner to that called for by their actual blood glucose values (zone E). χ^2-Analysis of the clinically significant errors (zones C–E) shown in Tables 2–4 demonstrates no differences in expected errors from one system to another ($\chi^2 = .8653$, NS).

The correlation coefficients between filter-paper–generated blood glucose values and simultaneously collected plasma glucose values determined with a Technicon RA-1000 autoanalyzer measured immediately and after ~8 days of storage are identical ($r = .98$) (D.C., M. Moll, L.A.G.-F., J. Savory, and S. Jones-Garrison, unpublished data). However, the EGA of these data sets shows that the clinical accuracy of delayed measurements (38% zone A, 57% zone B) is not identical to the accuracy of those measured immediately after collection (93% zone A, 7% zone B).

TABLE 3
Error grid analysis of accuracy of visually interpreted reagent strip blood glucose reading

Zone	Glucostix (n = 969)
A	79.4
B	16.7
C	0.5
D	3.2
E	0.2

Values are percentages. $r = .91$.

TABLE 4
Error grid analysis of accuracy of Memory Glucometer II blood glucose readings

Zone	Lab personnel* (n = 208)	Patients† (n = 240)
A	83	73.9
B	15	20.3
C	0	0.5
D	2	4.8
E	0	0.5

Values are percentages.
*$r = .87$; †$r = .85$.

Recently, the clinical laboratories in our hospital decided to determine the accuracy of three glucose meters for possible use on the hospital wards. The Technicon RA-1000 autoanalyzer was used as the reference system. Regression analysis and standard error of duplicate estimates were determined for each meter [Accucheck II (Bio-Dynamics, Boehringer Mannheim, Indianapolis, IN), Glucometer II, Glucoscan 9000 (Lifescan, Mountainview, CA)], and a decision was made that one system (Accucheck II) provided more accurate data than the other two (Table 5). On closer inspection of their data by EGA, it is seen that, although there are differences in the standard errors of estimates with these three systems, there are no clinically relevant differences between them and each is acceptable for clinical use and decision making.

The usefulness of EGA to the reader of the scientific literature is illustrated by the following examples of data published by other investigators. Gifford-Jorgensen et al. (37) compared the accuracy of five different reflectance meters. They determined, by analysis of variance (ANOVA) and Dunnett's multiple-comparisons test, that one of the five systems tested produced glucose readings that were significantly different from those obtained by their reference laboratory. By applying the EGA grid to the graphs published in their article, however, results from all five of the systems described fall within the clinically acceptable zones A and B, and therefore none of these meters would be expected to produce results that might lead to dangerous or erroneous treatment decisions by patients. A similar analysis of three reflectance meters was performed by Nelson et al. (21). With linear regression analysis and ANOVA, this group concluded that one system produced the best predictive values over the entire range of blood glucose tested (30–399 mg/dl), whereas another system underestimated blood glucose values >100 mg/dl, and the third system read consistently high in the range of 30–99 mg/dl. EGA of these data showed that

TABLE 5
Accuracy of blood glucose values obtained with three different reflectance meter systems compared with Technicon RA-1000 hexokinase reference system

	Glucometer II	Glucoscan 9000	Accucheck II
Statistical analysis			
n	74	78	68
Correlation coefficient	.972	.959	.99
Linear regression equation	$y = 1.036x + 2.09$	$y = 1.08x + 2.5$	$y = 0.918x + 5.84$
Standard error of estimates	13.0	16.5	8.4
Error grid analysis			
Zone A	97.3	94.9	98.5
Zone B	1.3	2.5	0
Zone C	0	0	0
Zone D	1.4	2.6	1.5
Zone E	0	0	0

Error grid analysis values are percentages.

indeed their most accurate system produced results entirely within the clinically acceptable zones A and B. However, both of the other systems produced only one data point each in a clinically unacceptable range (both in zone D—failure to detect and treat errors). Therefore, we conclude that each of these systems is clinically accurate and that the conclusions reached by the authors' analysis of their data, specifically that one system underestimated blood glucose values >100 mg/dl and the other read consistently high in the 30–99 mg/dl range, are not of clinical importance.

DISCUSSION

The usefulness of EGA for displaying and evaluating the clinical accuracy of patient-generated blood glucose values with five different reflectance meters has been demonstrated. EGA has also been used to present the clinical accuracy of a visually interpreted glucose reagent strip. In addition, we have shown that, although a clinical laboratory analysis of three different reflectance meters suggested that one of the meters tested was most accurate, by EGA the difference in accuracy observed would not lead to more inaccurate therapeutic decisions. Finally, we have shown that, although correlation coefficients for filter-spot glucose analysis performed immediately and after 8 days of storage are identical, delayed analysis leads to a decrease in the clinical accuracy of this technique. In each of these studies the correlation coefficients generated misrepresent the clinical relationship between the data sets and do not permit the reader to evaluate the clinical accuracy of the data. We have also used EGA in our research to evaluate the accuracy of patients' estimates of their blood glucose levels and to compare the changes in their ability to estimate their glucose over time and after intensive blood glucose awareness training (40,41).

Previous evaluations of blood glucose accuracy have focused on the statistical but not the clinical significance of the glucose values obtained with various monitoring systems. A patient's or technician's ability to generate glucose values that are statistically accurate by standard analyses does not always translate into a high percentage of clinically accurate and acceptable blood glucose readings. Despite the various findings presented in the literature, we are unable by EGA to identify any particular SMBG system that produces a high percentage of clinically inaccurate and unacceptable blood glucose readings.

EGA represents an important and useful methodological contribution to the evaluation of accuracy of glucose monitoring. It accurately and adequately addresses the question of the clinical importance of data being generated on location at medical centers and laboratories and the statistical data being reported in the literature. In addition, EGA identified the most common types of errors made by patients who determine their own blood glucose levels. The researcher or clinician can easily use this system to analyze his/her own data. Although the EGA is based on treatment goals and objectives used in our medical center, it can easily be modified to reflect target blood glucose ranges and treatment assumptions unique to other settings. For example, changing the target blood glucose range from 70–180 to 60–120 mg/dl, as might be done during pregnancy, could result in a different assessment of clinical accuracy. With this target zone (60–120 mg/dl), a reanalysis of the Glucometer II data demonstrates an increase in clinically acceptable (88.9% zone A, 11.1% zone B) and a decrease in clinically inaccurate or unacceptable (0% zones C–E) blood glucose values compared with the original analysis (Table 2).

In conclusion, EGA has been shown to be a clinically important tool for the evaluation of SMBG systems and comparing the accuracy between system- and reference-generated glucose values. We strongly suggest the adoption of EGA as a standard method for analyzing and reporting the clinical relevance of statistical data relating to SMBG.

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