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Newer Portable Glucose Meters—Analytical Improvement Compared with Previous Generation Devices?

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Background: **Newer glucose meters are easier to use, but direct comparisons with older instruments are lacking. We wished to compare analytical performances of four new and four previous generation meters.**

Methods: **On average, 248 glucose measurements were performed with two of each brand of meter on capillary blood samples from diabetic patients attending our outpatient clinic. Two to three different lots of strips were used. All measurements were performed by one experienced technician, using blood from the same sample for the meters and the comparison method (Beckman Analyzer 2). Results were evaluated by analysis of clinical relevance using the percentage of values within a maximum deviation of 5% from the reference value, by the method of residuals, by error grid analysis, and by the CVs for measurements in series.**

Results: **Altogether, 1987 blood glucose values were obtained with meters compared with the reference values. By error grid analysis, the newer devices gave more accurate results without significant differences within the group (zone A, 98–98.5%). Except for the One Touch II (zone A, 98.5%), the other older devices were less exact (zone A, 87–92.5%), which was also true for all other evaluation procedures.**

Conclusions: **New generation blood glucose meters are not only smaller and more aesthetically appealing but are more accurate compared with previous generation devices except the One Touch II. The performance of the newer meters improved but did not meet the goals of the latest American Diabetes Association recommendations in the hands of an experienced operator.**

Self-monitoring of blood glucose (SMBG)[1] is widely used because intensive insulin therapy has become a standard treatment regimen in type 1 diabetic patients *(1–3)* and recommendations for type 2 treatment are being newly structured *(4)*, with increases in SMBG expected. Besides patients, nurses and technicians increasingly use portable glucose meters for bedside glucose measurements in hospitals and for in-home patient care. Because bloodless glucose measurement is still restricted to research and is far from clinically routine *(5, 6)*, new, smaller, and fast-acting portable glucose meters are being developed. The criteria for clinical evaluation of glucose meters have been improved *(7, 8)*, and the performance of meters is reported regularly *(9–12)*. To determine whether new generation glucose meters perform as well as or better than previously developed devices, we compared commonly used newer with older meters.

Materials and Methods

Capillary blood samples were taken at room temperature (~20 °C) from type 1 and type 2 diabetic patients attending our outpatient clinic; these samples represented blood glucose values from 2.2 to 22.2 mmol/L to cover all clinically relevant ranges. Blood glucose was measured with two devices from the following brands: for the "old" meters, the Accutrend® [Europe (Eu)] or Accu-Chek® Easy™ [United States (US); Boehringer Mannheim, Mannheim, Germany], the Companion™ 2 (Eu and US; MediSense, Birmingham, UK, and Cambridge, MA), the Glucometer® 3 (Eu and US; Bayer Diagnostics, Munich, Germany, and Miles Diagnostics Division, Elkhart, IN), and the One Touch® II (Eu and US; LifeScan, Johnson & Johnson, Milpitas, CA); for the "new" meters, the Glucocard™ (Eu) or Glucometer Elite® (US; Menarini Diagnostics, Florence, Italy, and Bayer Diagnostics), the Glucometer Esprit™ (Eu) or Glucometer Dex™ (US; Bayer

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[1] Nonstandard abbreviations: SMBG, self-monitoring of blood glucose; Eu, Europe; US, United States; and ADA, American Diabetes Association.

Diagnostics), the Glucotouch™ (Eu) or SureStep® (US; LifeScan, Johnson & Johnson), and the Glucotrend® (Eu) or Accu-Chek Instant™ (US; Roche Diagnostics, Mannheim, Germany). Three meters use electronic sensor techniques (Companion 2, Glucometer Esprit, and Glucocard), the other meters use reflectance techniques. A total of 1987 measurements (on average, 248 measurements for each brand) were performed using the same blood sample for comparison with our glucose oxidase method (comparison method) performed on a Beckman Analyzer 2 (Beckman). The two devices of each brand were regularly exchanged with each other after every 5–10 measurements. Two to three different lots of strips were used for measurements with each brand of meter. Calibration was performed daily with strips or calibration solutions. All measurements were performed according to the manufacturers' recommendations by the same experienced technician. Measurements <2.2 and >22.2 mmol/L as well as those that were indicated as "low" or "high" by the devices were excluded from evaluation. We also excluded samples with hematocrit values <30% and >60%.

STATISTICS

Values were analyzed for clinical relevance by determination of the percentage of values within a maximum deviation of 5% from the reference value, according to recommendations by the American Diabetes Association (ADA) *(1, 2)*. In addition, the error grid analysis method of Clarke and co-workers *(7, 8)* was used to assess accuracy. The error grid defines the *x*-axis as the reference blood glucose and the *y*-axis as the value generated by the glucose meter. The graphic model describes clinically relevant deviations using asymmetrically arranged areas for glucose ranges between 3.9 and 22.2 mmol/L. The agreement between glucose meter values and reference glucose values is expressed by different zones and thus gives the accuracy of the meters: zone A, clinically accurate; zone B, clinically irrelevant deviation by >20% from the reference; zone C, unnecessary overcorrection possible; zone D, "dangerous failure to detect and treat" errors; and zone E, "erroneous treatment" danger. To assess the overall deviation of the devices, we also calculated the mean (SD) difference from the Beckman glucose oxidase results *(13)*. To determine within-run precision, the CVs for 10 measurements in series were calculated for three different clinically relevant blood glucose ranges: 2.9–3.9 mmol/L, 9.1–10 mmol/L, and 15–15.7 mmol/L.

Results

The percentage of values within a maximum deviation of 5% from the reference value as recommended by the most recent ADA conference on SMBG is shown in Table 1. The newer meters (Glucocard, Glucometer Esprit, Glucotouch, and Glucotrend) were significantly better when compared with previous generation meters (Accutrend, Companion 2, Glucometer 3, and One Touch II). The only exception for the older devices was the One Touch II, which performed at least as well as the Glucometer Esprit and the Glucocard. None of the devices reached the ADA recommendations of 100% of readings within a 5% deviation limit. The differences (mean ± SD) between meter-generated results and the values measured with our comparison method are shown in Table 2. The Glucometer Esprit, Glucotouch, and Glucotrend slightly overestimated (positive mean percentage) and the Glucocard slightly underestimated (negative mean percentage) the "true" comparison glucose values. For the previous generation meters, this method of comparison gives much higher differences: overestimation of >10% for the Glucometer 3 and underestimation of >10% for the Companion 2.

Table 1. Percentage of blood glucose values within a ±5% deviation from the reference values.[a]

Devices	Percentage of values
Newer	
Glucocard	50
Glucometer Esprit	49
Glucotouch	53.5
Glucotrend	57
Old	
Accutrend	45
Companion 2	32.5
Glucometer 3	33.5
One Touch II	50

[a] n = 1987.

The error grid analysis is shown in Fig. 1. For all newer meters, 98% of values were within zone A and 100% were within zones A + B compared with the Accutrend, Companion 2, and Glucometer 3, which gave a few values in "risk zones" C, D, and E. Glucometer 3 had estimations in a low glucose range (<4 mmol/L) in zone E and in a high glucose range (>13 mmol/L) in zone C, Accutrend and Companion 2 gave values only in a high glucose range (>13 mmol/L) in zone D. Again, One Touch II was an exception among the older devices, performing similar to the new generation meters.

The CVs for measurement in series, which were used

Table 2. Differences between meter-generated and comparison method values.[a]

Devices	Difference, mean ± SD, %
Newer	
Glucocard	−2.0 ± 6.6
Glucometer Esprit	2.2 ± 1.5
Glucotouch	1.1 ± 0.8
Glucotrend	1.6 ± 1.3
Old	
Accutrend	−8.6 ± 8.6
Companion 2	−13.5 ± 10.6
Glucometer 3	10.8 ± 10.0
One Touch II	5.8 ± 4.7

[a] n = 1987.

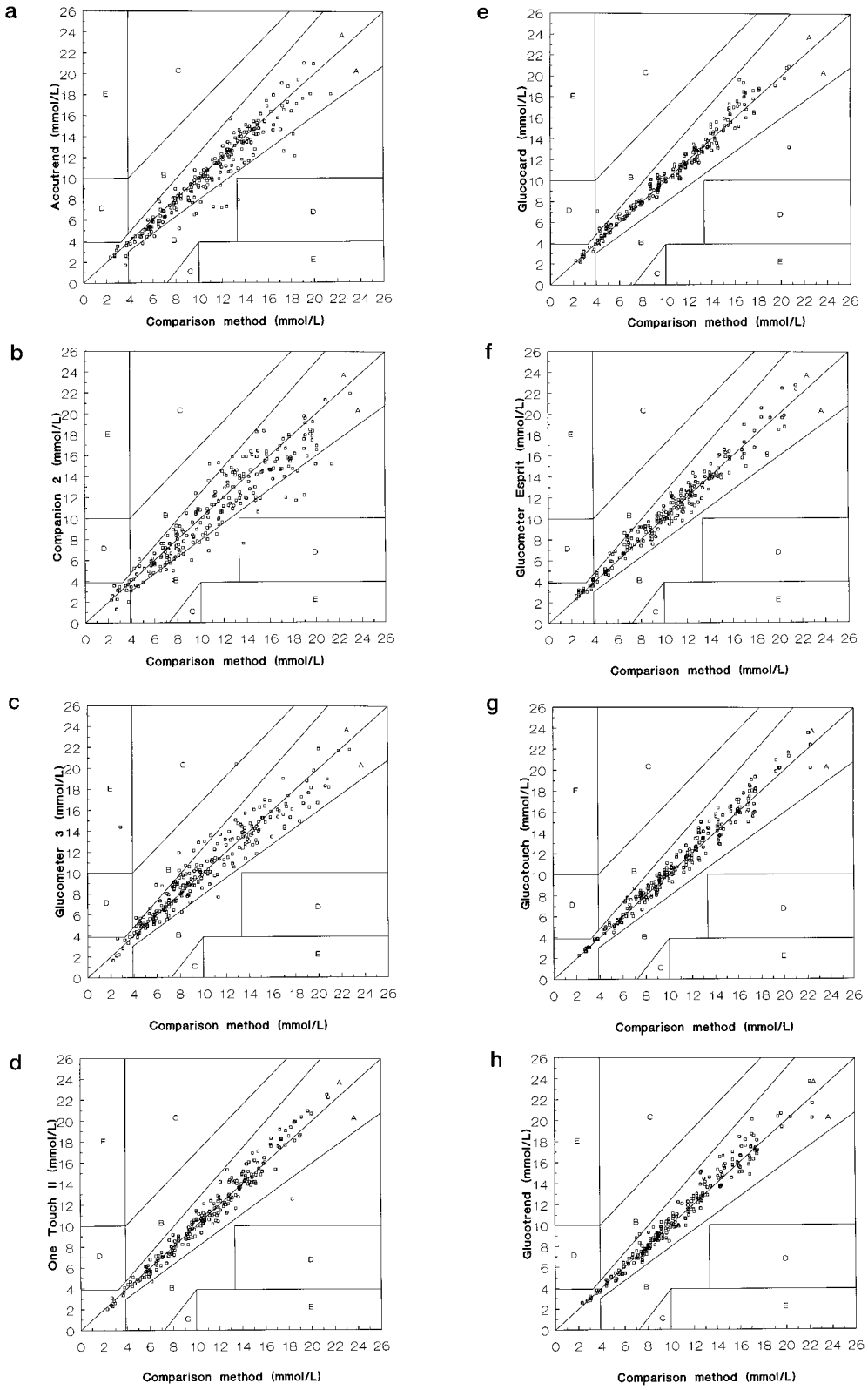

Fig. 1. Error grid analysis for each blood glucose meter.

Readings of glucose meters are plotted against values from the comparison method. The agreement of glucose meter values and reference glucose values is expressed by different zones and thus gives the accuracy of the meters: *zone A*, clinically accurate; *zone B*, clinically irrelevant deviation by >20% from the reference; *zone C*, unnecessary overcorrection possible; *zone D*, dangerous failure to detect and treat errors; *zone E*, erroneous treatment. *Panels a-d* are older devices; *panels e-h* are newer devices. *a*, Accutrend; *b*, Companion 2; *c*, Glucometer 3; *d*, One Touch II; *e*, Glucocard; *f*, Glucometer Esprit; *g*, Glucotouch; *h*, Glucotrend.

to define precision of the devices, are shown in Table 3. The Glucometer Esprit performed the worst, especially with respect to low glucose ranges, where only the old meter Companion 2 showed even more dispersion.

Discussion

In this study, we compared four new generation portable glucose meters with four previous generation meters with respect to accuracy and precision. According to recommendations in previous studies *(7, 8, 14)*, we chose brands of glucose meters that are used frequently in clinical and outpatient care. For our evaluation, we did not use statistical methods, such as linear regression analysis, that have only limited value for clinical evaluation of glucose meters. We chose the error-grid analysis as one of the clinically most relevant approaches *(12, 14)*. With the newer glucose meters, 100% of measurements were within error grid zone A (accurate zone) and zone B (clinically irrelevant deviation). For the older meters, this was true only for the One Touch II; the other meters of this generation gave a few values in zones C, D, and E, making clinically incorrect decisions based on the measured values at least possible. Because error-grid analysis represents only one analytical view, we added a set of analyses according to recommendations of the ADA. According to these recommendations, the accuracy of measurements is expressed by the percentage of deviations from the reference value. A previously recommended deviation of within 10% for 100% of measurements was recently replaced by recommendations for a target variability of <5% *(2)*. Although only 49–56% of the values measured with the new meters met the new ADA criteria, improvement was significant: the older meters reached these target values in ≤25% of measurements. The reason for this improved performance by the newer glucose meters is probably attributable to both technical improvements in the devices and the reduced blood volumes necessary for measurement. The newer meters need only 3–5 μL compared with 10–50 μL for previous systems, which makes mistakes in application of blood drops to test strips unlikely. Strips such as those used for the Glucocard take up only a limited amount of blood for measurement. These advantages are combined with fast measurement within 20–60 s; memory function for up to 300 measurements; and smaller, more aesthetically appealing devices. However, only the Glucotouch is still equipped with test strips for visible control, which may help detect meter dysfunction.

We found no substantial difference with respect to the technical equipment of the tested meters using either reflectance or electronic sensor technique. Whether additional new techniques will help meet the goals of the latest ADA criteria is thus questionable. To justify these stringent criteria, one must also be aware of a broad variability in the skill of users. SMBG, meanwhile, is performed by so many patients and healthcare personnel in various settings that user errors may impair results in daily practice despite improvement in analytical performance. As implemented by the Diabetes Control and Complications Trial *(3)* and the United Kingdom Prospective Diabetes Study *(15)*, current standards for diabetes care *(4)* include increasing the frequency of SMBG by an increasing number of intensively treated type 1 and type 2 diabetic patients. Therefore, in addition to improvements in technical accuracy, appropriate training of the patients and healthcare personnel using glucose meters is the a mainstay of well-established SMBG. In addition to regular calibration and maintenance of meters, frequent comparison of function with values obtained by a reference laboratory method seems advisable.

In summary, the performance of the newer portable glucose meters when clinically assessed under laboratory conditions was substantially improved compared with all previous generation devices except for the One Touch II. These results may be extrapolated but have yet to be demonstrated in daily use by patients and healthcare personnel. Until reliable noninvasive blood glucose measurement methods are available for everyday clinical use, further improvement of currently available devices to meet the ADA standards is necessary.

Table 3. Mean CVs for measurements in series for three different blood glucose concentrations.

	CV, %		
Blood glucose meter	Sample A (2.9–3.9 mmol/L glucose)	Sample B (9.1–10.0 mmol/L glucose)	Sample C (15.0–15.7 mmol/L glucose)
Newer devices			
Glucocard	4.2	3.8	2.1
Glucometer Esprit	13	6.2	2.0
Glucotouch	1.1	1.9	1.7
Glucotrend	3.4	2.2	2.7
Old devices			
Accutrend	7.0	2.5	1.5
Companion 2	16	4.5	1.0
Glucometer 3	7.5	1.6	2.0
One Touch II	7.0	1.5	0.8

Blood glucose meters and strips were kindly provided by the manufacturers.

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