Clinical Evaluation of Computer-Assisted Self-Monitoring of Blood Glucose System

David G. Marrero, PhD
Kathleen K. Kronz, BS
Michael P. Golden, MD
James C. Wright, MD
Donald P. Orr, MD
Naomi S. Fineberg, PhD

The Glucometer M Diabetes Management System includes a glucose-reflectance meter with memory that can interface with a microcomputer for data manipulation and analysis. We evaluated the system in a short-term randomized control trial to determine its impact on metabolic control, self-monitoring of blood glucose (SMBG) testing behaviors, regimen self-adjustment, understanding of insulin-dependent diabetes mellitus (IDDM) treatment, attitudes about SMBG, and perceived quality of patient-physician interaction. Twenty-nine adolescent subjects (experimental) with IDDM were randomly assigned the Glucometer M system for 4 mo. Twenty-eight control subjects used meters without memory. All subjects returned twice to the clinic at 2-mo intervals during the study. At clinic visits, both groups reviewed their SMBG data with their physician. Reviews on experimental subjects were conducted with computer-generated data formats. Control subject reviews used traditional logbooks. Both groups showed a significant drop in glycosylated hemoglobin during the study period ($P < .001$); however, there were no between-group differences. There were also no differences in SMBG testing behavior or self-reported regimen self-adjustment between groups or within groups compared with baseline. Compared with control subjects, experimental subjects indicated a significant increase in self-reported understanding of IDDM treatment ($P = .002$), perceived importance of testing ($P = .006$), and the quality of interaction with their physician ($P < .001$). These data suggest that use of computer-assisted SMBG systems in the outpatient setting does not improve metabolic control over 4 mo. It may, however, contribute to improving communication between the patient and health-care providers. *Diabetes Care* **12:345–50, 1989**

From the Departments of Pediatrics and Medicine, Indiana University School of Medicine, Indianapolis, Indiana.
Address correspondence and reprint requests to David G. Marrero, PhD, Regenstrief Institute, 1001 West Tenth Street, Indianapolis, IN 46202.

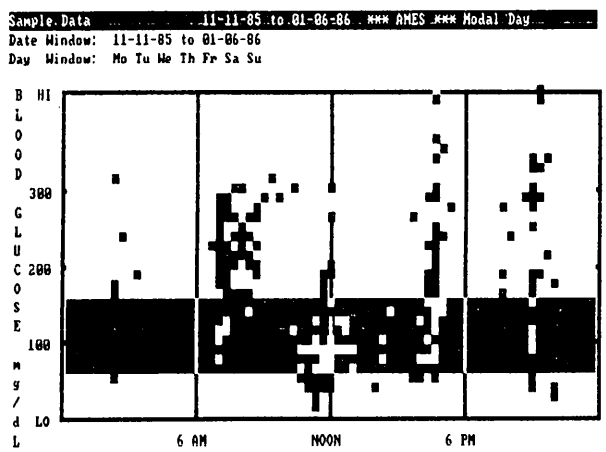
Self-monitoring of blood glucose (SMBG) by patients with insulin-dependent diabetes mellitus (IDDM) has become an integral component of treatment (1–4). However, errors in obtaining and recording SMBG results potentially limit the interpretability of the data by health-care providers, and thus their therapeutic value. Errors in technique account for some inaccuracy in SMBG testing. Errors specifically related to recording results include inaccurate transcription, illegibility, failure to record tests, and fabricating data (5–9). Even when data has been accurately recorded, its volume may preclude meaningful interpretation. In response to these issues, new SMBG systems have been developed that use microcomputer technology to automate the recording and assist in the interpretation of SMBG data (10). This study investigated the clinical usefulness of the Glucometer M Diabetes Management System (GDMS; Ames, Elkhart, IN) in a randomized control trial with a pediatric population in an outpatient clinical setting (11). In theory, GDMS provides physicians with more consistently accurate and verifiable SMBG data than is traditionally obtained with noncomputerized systems (12). In addition, the ability of GDMS to quickly manipulate large volumes of data coupled with the various methods available for data analysis may improve interpretation and discussion of results with patients. Thus, we hypothesized that use of the GDMS system would improve *1*) patient metabolic control, *2*) patient-physician communication, *3*) patient understanding of treatment, and *4*) patient attitudes toward SMBG.

MATERIALS AND METHODS

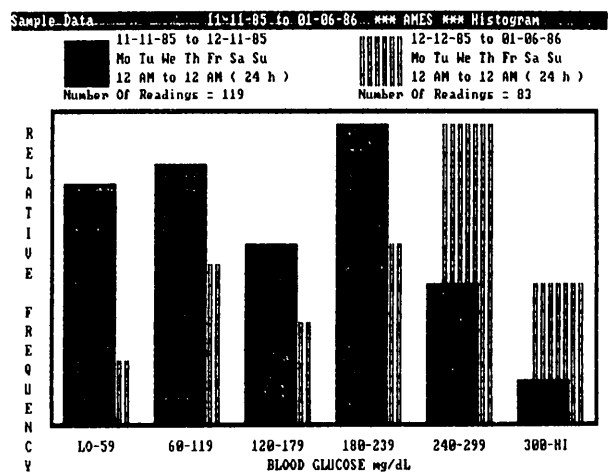
Memory-reflectance meter. The Glucometer M blood glucose meter contains a microchip that automatically stores up to 338 glucose test results, noting the time and date of each. There are three marker buttons to identify special events associated with a given test and to allow control/calibration readings to be deleted from analysis. A recall key is also provided that sequentially displays all stored results including date, time, and glucose values. Finally, the meter will calculate and display the average blood glucose for the previous 14 days. Data stored in the meter are uploaded directly to a microcomputer for analysis.

Patient management software. Glucofacts Data Management System Software is designed as a data management program to simplify trend/pattern analysis and present glucose data in five statistical and graphic format options (Fig. 1). These include *1*) modal day, in

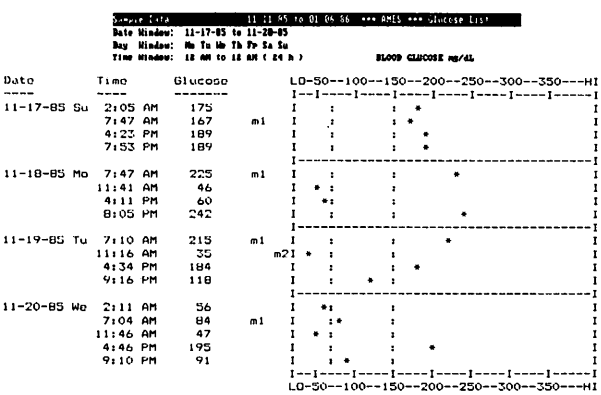
A



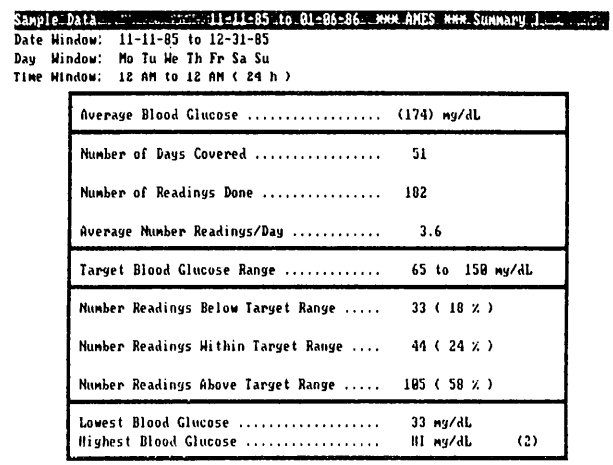
B



C



D



E

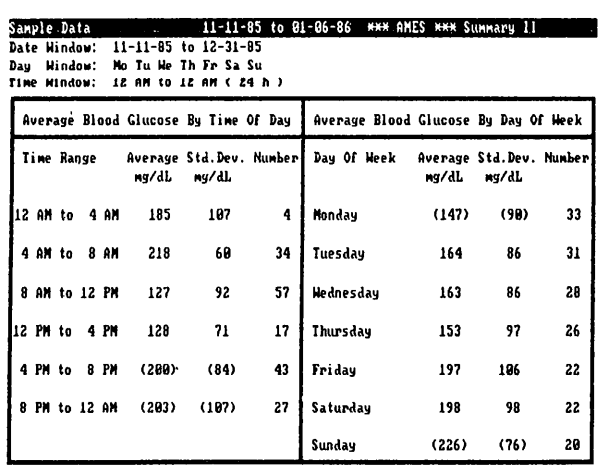


FIG. 1. Statistical and graphic format options for data management system. *A*: modal day; *B*: histogram; *C*: glucose list; *D*: summary 1; and *E*: summary 2.

which glucose levels are plotted by time over 24 h and data are overlaid as if all readings were taken on a single day; 2) histogram, which provides a bar-graph analysis of data showing the frequency of glucose values that fall within individually defined concentration ranges and displays side-by-side analysis of different portions of the data dates, days, and times; 3) glucose list, which displays all glucose readings stored in the meter by day and time and all marked data (including deletions) in both tabular and graphic forms; 4) summary 1, which displays statistics about mean glucose values; number and percentage of readings below, within, and above a specified target range; and the highest/lowest readings; and 5) summary 2, which provides means ± SD for test results by time of day and by day of week.

Microcomputer. An IBM PC-XT configured with 512k bytes RAM, 1 double-sided 5¼ diskette drive, and a 10 megabyte hard disk were used for data management and presentation. An Amdex 600 color monitor was used to display the data during clinic visits with subjects.

Subjects. The study population consisted of patients with IDDM from the James Whitcomb Riley Hospital for Children in Indianapolis, Indiana. To be eligible as subjects, patients had to be between the ages of 10 and 18 yr and have had diabetes for >1 yr. Patients selected had demonstrated a regular history of keeping outpatient appointments and had completed a multidisciplinary education program similar to one previously described for preschoolers (13). All subjects and their parents had demonstrated proficiency in SMBG and had been taught basal and compensatory insulin supplementation. The outpatient setting was the Pediatric Model Demonstration Unit of the Indiana University Diabetes Research and Training Center, that was staffed by nurse practitioners, dietitians, and social workers. Patients were excluded if they had existing psychopathology and/or learning disabilities.

Subjects were stratified according to age and sex and randomly assigned to the experimental or control condition. Patients in the experimental condition used a Glucometer M reflectance meter with memory to record their SMBG results. In addition, they were asked to record the results in a logbook. During clinic visits, they reviewed their data with their physicians with the various data formats produced by the GDMS software. Patients in the control condition used reflectance meters without memory and reviewed their SMBG data with physicians with traditional logbooks.

The final sample consisted of 29 experimental subjects (18 males, 11 females), average age 14.7 ± 2.2 yr with a mean duration of IDDM of 5.2 ± 3.1 yr, and 28 control subjects (17 males, 11 females), average age 14.1 ± 2.3 yr with a mean duration of IDDM of 6.2 ± 3.9 yr.

Metabolic control. Metabolic control was assessed by total stable glycosylated hemoglobin (HbA_1) measured by the immunoassay research core of the Indiana University Diabetes Research and Training Center with the microcolumn ion-exchange method (14). The labile fraction was removed with an aldimine eliminator (Isolab, Akron, OH). This procedure has been shown to be equivalent to saline incubation. The reference range in the nondiabetic population for this test in our laboratory was 5.5–7.5%. Blood samples for HbA_1 determinations were collected at each visit.

SMBG testing data. The logbooks of subjects in both conditions were collected at baseline and at each scheduled clinic visit. The average number of readings for each day were tabulated. In addition, experimental subjects' SMBG data stored in their Glucometer M meters was off-loaded at each visit and compared with their logbook data.

Physician time reviewing SMBG data. During the physician-patient interviews, the number of minutes each physician spent reviewing SMBG records with subjects in both groups was recorded by an observer.

Patient interviews. With a standard structured technique, subjects in both groups were interviewed by one of the two investigators (D.G.M. and K.K.K.) twice at each clinic visit before and after being seen by a nurse educator and physician. The previsit interview contained questions concerning frequency and time of SMBG testing, frequency of self-adjustment of their regimen in response to exercise, diet, and monitoring results, and the number and types of deviations from their prescribed regimen. In the postvisit interview, subjects were asked questions concerning perceived quality of interaction with their physician during the clinic visit, perceived change in understanding of IDDM and its treatment, likelihood of improving control, and importance of testing.

Procedure. Patients were invited to participate in the study during a regularly scheduled visit. After signing an Indiana University Institutional Review Board approved informed consent form (parents and patient), they were randomly assigned to experimental or control groups.

Subjects were seen at baseline and 2 and 4 mo during the study. During the first visit, it was explained to subjects that during the course of the study their physician would be reviewing their SMBG data with them during clinic visits and asking them to provide explanations for various outcomes. It was further explained to experimental subjects that this review and discussion would be conducted with GDMS software on a microcomputer in the examining room. The memory function of the reflectance meter was explained and the five data formats were demonstrated with a sample data set. Control patients were asked to demonstrate their monitoring technique and were reeducated when necessary. Experimental subjects exchanged their own meter for a Glucometer M and were trained in its use. Subjects in both groups were supplied with sufficient reagent strips to last until their next scheduled clinic appointment in 2 mo.

During the second visit, subjects were interviewed before being seen by a nurse practitioner and physician. During the clinic visit, the physician reviewed SMBG

data with the subject. Experimental subjects' data were off-loaded to the microcomputer located in the examining room and reviewed on the computer monitor with GDMS software. Logbooks were used to review insulin doses, illnesses, and diet or exercise notes. In both conditions, a nonphysician researcher (D.G.M. and K.K.K.) was present to time and record the discussion between patient and physician.

The three physicians participating in the study followed the same protocol for reviewing SMBG results. Subjects in both groups were asked about the frequency of their monitoring, particular times they were having trouble with metabolic control, and possible reasons for these problems. They were also asked to suggest possible solutions to the identified problems. For the experimental condition, physicians followed a protocol for the order in which the computerized data formats were presented during review of the subject's data. The order was summary 1, modal day, summary 2, and glucose list. Once the physician had reviewed all of the screens one time in this order, he could go back to any screen. After the clinic appointment, all subjects were reinterviewed by the nonphysician researcher. The same protocol was followed for the third visit with the exception of experimental subjects exchanging the Glucometer M for their original meters.

Statistical methods. Data were analyzed with SPSSX. Results are given as means ± SD. Comparisons of continuous variables between or within groups used group and paired *t* tests. Contingency tables were analyzed with Fisher's exact test (15). To compare changes over time in the two groups, repeated-measures analysis of variance was performed. This provides three statistical tests (effect of study group, change over time, and an interaction between study group and time). The latter test indicates if the changes over time are different for the two study groups (16).

RESULTS

Table 1 shows the changes that occurred in HbA_1 during the study period. Both groups showed a significant decrease in HbA_1 during the study period ($P < .001$); however, there were no between-group differences. Table 2 shows the average frequency of SMBG testing per day. Both groups showed a transient rise in the average number of readings recorded in their logbooks ($P = .01$) that returned to baseline numbers at visit 3. There were no significant between-group differences. In addition, there were no significant differences between the electronically stored and handwritten logbook glucose readings of the experimental group at visit 2 ($P = .81$) or visit 3 ($P = .56$). There were also no significant differences in self-reported SMBG testing behavior (i.e., frequency or time of testing), the number and types of deviations from the prescribed regimen, or in regimen self-adjustment between or within groups compared with baseline for either visit 2 or visit 3.

Table 3 shows the average number of minutes spent by the physicians reviewing SMBG data with subjects in both groups. Significantly more time was spent with experimental subjects at visits 2 and 3. When compared with control subjects, experimental subjects reported a significant increase in the perceived quality of interaction with their physician ($P < .001$), perceived understanding of their diabetes and its treatment ($P = .002$), and the perceived importance of testing ($P = .006$). Most subjects in both conditions reported at visit 3 that the interaction with their physician would help them to improve their control (yes/no; experimental 27/2 and control 22/5), but there were no significant between-group differences ($P = .24$).

TABLE 1
Changes in glycosylated hemoglobin during study period

	Experimental	Control
Baseline	10.3 ± 1.8	10.8 ± 2.0
Visit 2	9.2 ± 1.5	9.5 ± 1.7
Visit 3	9.3 ± 1.7	9.8 ± 1.7
Repeated-measures analysis of variance		
Group	$F = 1.1$	$P = .295$
Time	$F = 20.7$	$P < .001$
Interaction	$F = 0.3$	$P = .770$

TABLE 2
Average number of glucose readings per day

	Experimental	Control
Baseline	2.69 ± 0.80	2.64 ± 1.49
Visit 2	2.82 ± 0.70	2.83 ± 1.27
Visit 3	2.61 ± 1.16	2.66 ± 1.40
Repeated-measures analysis of variance		
Group	$F = 0.1$	$P = .992$
Time	$F = 4.7$	$P = .015$
Interaction	$F = 0.2$	$P = .844$

TABLE 3
Average number of minutes discussing self-monitoring of blood glucose results

	Experimental	Control
Visit 2	25.5 ± 9.7	19.6 ± 13.0
Visit 3	21.2 ± 10.7	12.9 ± 7.4
Repeated-measures analysis of variance		
Group	$F = 4.9$	$P = .035$
Time	$F = 10.3$	$P = .003$
Interaction	$F = 0.5$	$P = .487$

DISCUSSION

This study evaluated the effects of adding computer storage of SMBG results and computer-assisted data analysis to regular pediatric outpatient visits. Contrary to our first hypothesis, the experimental group did not demonstrate significant improvement in metabolic control relative to the control group. There was, however, a significant decrease in HbA_1 in both groups. Data did support our other hypotheses. In comparison with control subjects, experimental subjects perceived a better quality of interaction with their physicians, more satisfaction with their clinic visits, and reported better understanding of IDDM treatment and more positive attitudes toward SMBG.

The reasons that metabolic control improved in all study participants are not clear but are of potential interest. Subjects in both conditions did not report significant differences during the study in the manipulation of regimen factors that are traditionally associated with variability in metabolic control, i.e., SMBG testing behavior (frequency or timing), deviations from the prescribed diet, exercise, insulin regimen, and regimen self-adjustment. In spite of greater time spent discussing SMBG results with experimental group patients, there was a comparable decrease in the control group's HbA_1 values. Hence, the decreases observed in the experimental group are unlikely to be related to differences in time on task.

The structured protocol used for physician's discussion of monitoring results may have contributed to the improvement in metabolic control observed in both groups. Physicians asked the same type and series of questions in both groups and emphasized asking subjects to explain results and suggest strategies to ameliorate problems with glucose control. This increased emphasis on SMBG results may have stimulated a subject's response to the results that they failed to report during interviews. Whereas routine clinic visits included regular discussion of SMBG results, the intensity of discussion was greater in both study groups.

Differences in time on task probably account for the affective differences observed between the groups. Experimental subjects reported more positive perceptions about their encounter and greater perceived understanding of how to self-adjust their regimen than control subjects. The greater time spent discussing SMBG results may have contributed to this finding. It is interesting to note that the total time spent with patients during their entire clinic visit (~60 min) did not change before and during the study and was not different between groups. Although the protocol for reviewing SMBG results was the same for both groups, physicians spent more time discussing SMBG results with subjects with the GDMS. Therefore, we speculate that one benefit of computer-assisted systems is that they allow the health-care professional to spend less time organizing or transforming data and more time interpreting the results and discussing therapeutic options with patients.

The increase in physician attention to SMBG results may also account for the significant increase in the perceived quality of patient-physician interaction reported by experimental subjects. During the postvisit interviews, many of the experimental subjects said that they felt their physician was paying more attention to their monitoring records, explaining insulin adjustment principles in more understandable ways, and demonstrating more clearly the value of SMBG testing. These perceptions may help to explain the significant increase in the perceived importance of testing also reported by experimental subjects.

There are limitations in the design of the study that affect its generalizability. The sample size was small and the follow-up period short. Physicians could not be blinded to their patients' treatment condition; thus, the potential for bias exists. The study was conducted in a tertiary care setting in which diabetologists were responsible for treatment decisions. It may be that the effect of summarizing complex data into a simplified format would be different among primary-care physicians who are not as familiar with IDDM.

In conclusion, our data suggest that the use of computer-assisted SMBG systems, such as the one described in this study, do not in and of themselves improve metabolic control. They may, however, increase the amount of time spent discussing SMBG data during clinic visits. This additional time may contribute to improving communication between patients and their health-care providers and patient satisfaction with care delivery. Further studies are needed to address this issue, explore the educational potential of these systems, and investigate new applications of this technology.

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