Telematic Transmission of Computerized Blood Glucose Profiles for IDDM Patients

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Objective: To improve the analysis of self-monitoring of blood glucose (SMBG) and its communication between patients and physicians by a telematic transmission of computerized SMBG and to study the consequences of its use on glucose control of insulin-dependent diabetic (IDDM) patients. Research Design and Methods: A prospective randomized crossover trial with two 3-mo periods, one with SMBG recorded on traditional booklets (booklet period) and another with computerized SMBG transmitted to a central data base through a telematic network (telematic period), comprised the study. During the latter phase, patients could receive computerized SMBG analysis on individual terminals connected to the telephone network (Minitel system). Blood glucose recordings and HbA_{1c} were measured at inclusion and end of each period. Eleven pairs of IDDM patients on intensified insulin therapy were randomized within each pair to start with the telematic period (group A) or the booklet period (group B). Results: Telematic transmissions were successful (<1% failure rate). Although initial HbA_{1c} was low (6.7%), it declined during the telematic period ($\Delta = -0.41\%$) compared with the booklet period ($\Delta = +0.37\%$, $P = 0.05$). The percentage of low (<3.3 mM) blood glucose values correlated with HbA_{1c} changes during the telematic period ($r = 0.714$, $P = 0.0014$) but not the booklet period. The patients favored the telematic tool to analyze SMBG. Conclusions: Telematic transmission of SMBG is feasible. It can improve SMBG analysis and perhaps glucose control, therefore offering a new way of communication between diabetic patients and their physicians. ***Diabetes Care*** **14:130–34, 1991**

Diabetic patients are advised to practice self-monitoring of blood glucose (SMBG), although it is controversial whether this technique improves their metabolic control (1–3). One drawback may be the lack of reliability of SMBG recorded on traditional booklets; false results can be recorded by some patients (4,5). Also, large files containing capillary glucose levels can be cumbersome and discourage patients and physicians because of the intrinsic variability of blood glucose in insulin-dependent diabetes mellitus (IDDM) (6). New reflectance meters with memories, combined with a program adaptable on a personal microcomputer, improve reliability of SMBG and patient performance (7), but they may not help to improve chronic hyperglycemia (8). One possible explanation may be that SMBG must be better analyzed but also transmitted more rapidly between patients and physicians, because the way they communicate with each other is important in controlling diabetes (9).

We tried to improve communication between patients and physicians by transmitting computerized SMBG data through a telematic network. We used the French teletel videotex network (France Telecom) called Minitel. This telematic tool offers individual terminals, which give easy access to public or private data bases through the public telephone network, for information or communication purposes (10). It can be used on a large scale; ~33% of French homes are equipped with a Minitel terminal. It can be obtained for free from French Telecom. The tax rate is the same as for ordinary telephone calls. Therefore, it is much less expensive and more practical than a personal microcomputer for a nonselected population. It is available in countries other than France (e.g., ~200,000 Minitel terminals are used in the U.S.). In this study, we tested the feasibility of a network designed to transmit computerized SMBG and its impact on the metabolic control of IDDM patients. This study was performed with IDDM patients on intensified insulin treatment because they can benefit from intensive SMBG (11). Our ultimate goal was to offer a potential telematic alternative to the booklets traditionally used by such subjects.

RESEARCH DESIGN AND METHODS

The telematic network we used is shown in Fig. 1. Capillary glucose values were collected with memory-reflectance meters (Glucometer M, Ames, Elkhart, IN). They were connected to the telephone network by a Minitel terminal through a specially designed adaptor. This adaptor could store signals emitted from the Glucometer M and control their transmissions through the telephone network. Each individual could access the central data base with a standardized procedure. Thirty glucose values per minute could be transmitted to the central data base located in our ward (an IBM-PC-XT microcomputer Olivetti M24, Olivetti-France, Aubervilliers, France, with a 20-megabyte hard disk and an external modem). Patients could read from their terminals a listing of the values they had just sent and a brief computerized analysis, i.e., the number of values for the given time interval, the average blood glucose level, and the mean value by time of day and by day of week

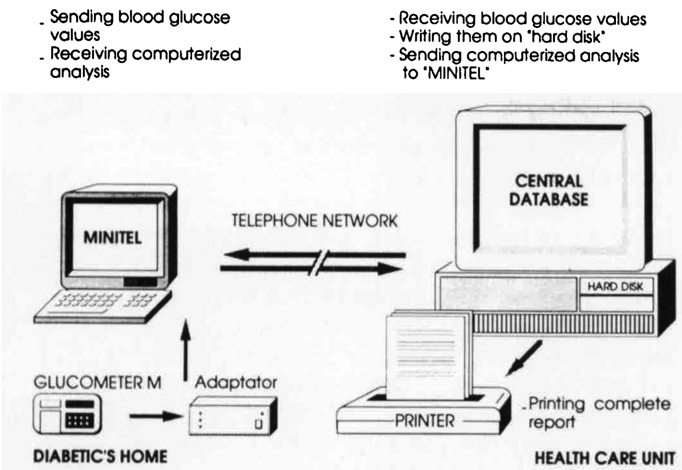

FIG. 1. Design of telematic network used by patients during telematic period of study (see METHODS for description).

(Fig. 2). Patients and physicians could also transmit simple individual messages with the Minitel terminal. The values stored in the central data base could be processed with the Glucofact Data Management System (Ames) described previously (8), and the corresponding data were printed for each outpatient visit. For this study, we preprogrammed a desirable interval of blood glucose between 3.3 and 10.1 mM.

Inclusion criteria were male or female, <60 yr of age with IDDM for >2 yr, a body mass index (BMI) <30 kg/m^2, attending our diabetes clinic for 6 mo, previously trained to intensive SMBG, on intensified insulin treatment (≥3 daily injections with conventional syringes or pens or portable insulin pumps), and a preceding HbA_{1c} level of <10%. Exclusion criteria were pregnancy or risk of pregnancy during the study, psychiatric disease, or any other seriously disabling disease. Our study consisted of 11 pairs of patients of the same sex (7 women and 4 men in each group), age (32 ± 14 yr), diabetes duration (13 ± 9 yr), and BMI (21.8 ± 3.2 kg/m^2). All patients gave their consent to participate in the study after being informed (1 pair consisted of 2 children whose parents gave consent).

After a 1- to 3-mo run-in period, patients within each pair were randomly assigned, in crossover fashion, to two successive periods of 3 mo each; one with a conventional reflectance meter (Glucometer II, Ames) and SMBG recorded on booklets (booklet period) and another with computerized SMBG assisted by telematics (telematic period). This crossover design was intended to reduce the novelty effect of a new technology on glycemic control (group A used the telematic period first, and group B used the booklet period) with pairs of patients with similar characteristics. During the telematic period, patients could use their Minitel as frequently as they wished, but in all cases, they transmitted their last results to the central data base the day preceding each outpatient visit. Patients could adjust their insulin as they wanted during the two periods. Every month they met their physicians during an outpatient visit to discuss SMBG results and treatment adjustments interactively. Total daily insulin dose and weight were also recorded. HbA_{1c} was measured three times; at entry and at the end of each 3-mo period. Neither patients nor physicians were aware of HbA_{1c} values. All capillary glucose values recorded during the booklet period were computerized retrospectively with the Glucofact Data Management System (Ames). A questionnaire was completed by patients at the end of the study to evaluate their opinions regarding the telematic device and to obtain their suggestions.

In a preliminary study, we compared blood glucose values measured with a conventional glucose oxidase laboratory method (x) to measurements made with Glucometer M (Ames) (y1) and Glucometer II (Ames) (y2): $y1 = 0.2 + 0.9x$ (mM), $n = 73$, $r = 0.96$; $y2 = 0.8 + 0.8x$ (mM), $n = 87$, $r = 0.98$. HbA_{1c} was measured with the Bio-Rad HbA_{1c} column assay (Richmond, CA; normal mean ± 1SD values 4.8 ± 0.4%; 12).

Statistical methods. We calculated from previous HbA_{1c} measures that the spontaneous variance of HbA_{1c} was 1.17 in patients enrolled in this study. Assuming a 1% drop in HbA_{1c}, we calculated a minimal sample size of 20 patients (i.e., 10 pairs) with a two-sided test with an α-error of 0.05 and a β-error of 0.20. To prevent unexpected dropout, 11 pairs of patients were recruited; one consisted of two children. One patient dropped out 2 mo after inclusion for reasons independent from diabetes. He was excluded from the final analysis.

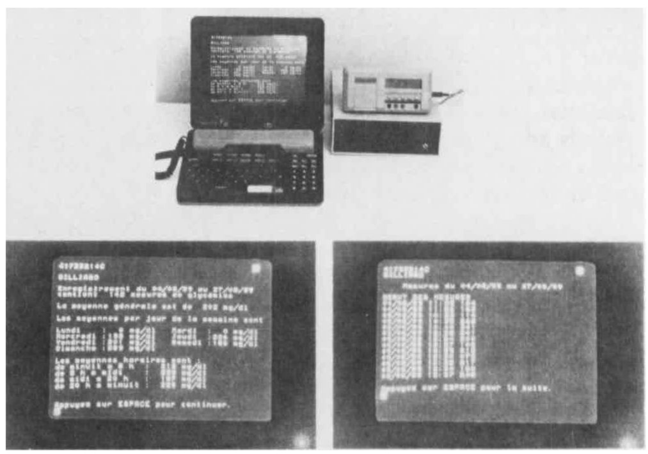

FIG. 2. Photographs of telematic tool as it was used in 1 diabetic patient's home. *Top*, Minitel terminal and Glucometer M on adaptor. Screen shows analysis of glucose values sent to central data base, which is magnified on *lower left* (written in French), which includes name of patient, number of values for given time interval, average blood glucose level, and blood glucose by time of day and day of week. *Lower right*, screen shows listing of individual values with their time and date. (For confidentiality purposes, name shown was not patient in study. Values shown were collected randomly in our ward for demonstration.)

The data were computed on an Apple MacIntosh II microcomputer with the 4th Dimension program (Apple Computer) for data management and the Statview II program (Abacus Concepts) for statistical analysis. Two-way repeated analysis of variance was used to study the interactions of time and of order of the two types of SMBG on the variables studied (13). Results are means ± 1SD with ranges in parentheses. Nonparametric tests were used for variables with a non-Gaussian distribution.

RESULTS

It took ~1 h for each patient to learn the telematic system. Eighty-one percent of the transmissions were successful during the first attempt. Afterward, only two failures occurred due to defects of the telephone network (i.e., <1% failure rate). All patients found the access procedure easy to perform. There were 3.1 ± 1.2 (range 1–4.5) accesses to the central data base per month per patient; 34 ± 9 (range 15–46) glucose values were transmitted during each access.

The physicians quickly became accustomed to the Glucofact Data Management System (Ames); only the first visit of the telematic period lasted longer than the other ones (19 ± 4 vs. 15 ± 3 min, $P < 0.05$).

The number and values of capillary glucose recorded on Glucometer M (Ames) or on booklets are shown in Table 1. Their frequency was comparable during the telematic and booklet periods: 3.33 ± 1.14 (range 1.1–6.1) vs. 3.12 ± 1.04 (range 1.2–5.4) per day. No order effect nor time effect was detectable. Mean capillary glucose values were also similar, as were the frequencies of low glucose values (Table 1). In group A, HbA_{1c} declined from 6.7 ± 1.4 to 6.0 ± 1.0% during the telematic period and increased to 6.8 ± 0.6% at completion of the booklet period. In group B, HbA_{1c} was 6.8 ± 1.0% at inclusion and 6.8 ± 0.9% at the end of the booklet period, and it declined to 6.7 ± 1.0% at completion of the telematic period (Table 1). Analysis of variance showed no order effect ($F = 1.47$, $P = 0.23$) or time effect ($F = 1.37$, $P = 0.27$), allowing for the comparison of the variations of HbA_{1c} from the beginning to the end of each period. A trend toward a decline was observed during the telematic period ($\Delta = -0.41 \pm 1.05\%$) compared with the booklet period ($\Delta = +0.37 \pm 0.82\%$, $P = 0.05$, Wilcoxon's test; Fig. 3). Total daily insulin dosages and BMI remained constant throughout the study (Table 1).

Because the lack of amelioration of capillary glucose recorded during the telematic period made a concomitant improvement of HbA_{1c} appear suspicious, we studied the relationship between HBA_{1c} changes and the frequency of low capillary glucose values (<3.3 mM), because reduction of one can be associated with an elevation of the other. The two variables were significantly correlated during the telematic period (r =

TABLE 1
Numbers and values of capillary glucose, HbA_{1c}, total daily insulin dosages, and body mass index of 21 insulin-dependent diabetic patients

	Inclusion	Month 3	Month 6
Recorded capillary glucose (n/day)			
Group A	2.9 ± 0.8 (1.9–4.2)	3.5 ± 0.9 (2.1–4.5)	3.2 ± 1.1 (1.5–4.6)
Group B	3.0 ± 1.1 (1.1–4.8)	3.1 ± 1.1 (1.2–5.4)	3.2 ± 1.4 (1.1–6.1)
Mean capillary glucose (mM)			
Group A	8.2 ± 1.6 (5.5–10.4)	8.2 ± 1.2 (6.0–9.2)	7.8 ± 1.6 (5.8–10.2)
Group B	7.9 ± 1.4 (5.4–10.6)	8.3 ± 1.4 (6.4–10.2)	8.8 ± 1.7 (6.5–12.8)
Percentage of values <3.3 mM			
Group A	6.8 ± 4.9 (1–15)	11.2 ± 7.8 (4–28)	9.4 ± 5.5 (1–20)
Group B	12.2 ± 8.9 (0–27)	9.3 ± 5.6 (0–17)	8.6 ± 6.5 (0–19)
Percentage of values >9.9 mM			
Group A	23.8 ± 17.1 (0–52)	29.0 ± 19.5 (0–51)	28.2 ± 13.2 (4–41)
Group B	27.2 ± 16.7 (0–55)	27.2 ± 14.9 (2–57)	33.4 ± 15.7 (15–68)
HbA_{1c} (%)			
Group A	6.7 ± 1.4 (5.0–9.2)	6.0 ± 1.0 (4.9–8.5)	6.8 ± 0.6 (5.6–7.9)
Group B	6.8 ± 1.0 (4.7–8.2)	6.8 ± 0.9 (4.7–7.9)	6.7 ± 1.0 (5.4–8.7)
Total daily insulin dosages (IU/day)			
Group A	34 ± 13 (18–60)	36 ± 15 (17–60)	36 ± 16 (17–62)
Group B	39 ± 16 (20–61)	36 ± 15 (14–56)	37 ± 14 (19–58)
Body mass index (kg/m^2)*			
Group A	21.8 ± 3.1 (17.5–28.6)	21.9 ± 2.8 (19.6–28.7)	21.8 ± 2.9 (18.6–28.6)
Group B	20.9 ± 3.6 (16.3–26.5)	21.9 ± 3.8 (16.3–26.9)	22.0 ± 3.7 (16.3–27.5)

In group A (see definition in METHODS), mo 3 was end of telematic period, afterward, patients changed to booklets. In group B, patients used telematics after completion of mo 3 up to mo 6. Results are means ± SD (ranges in parentheses).
*Children were excluded from calculations.

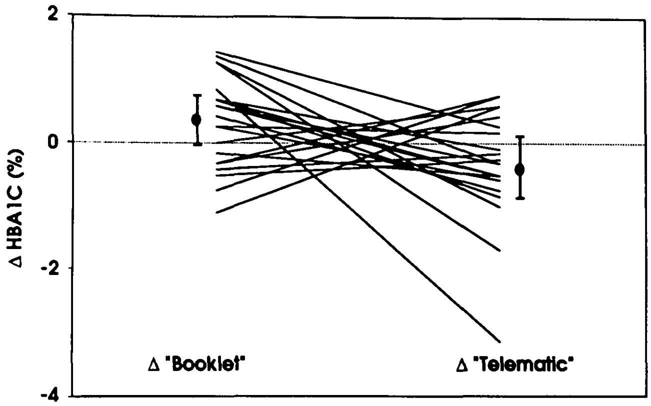

FIG. 3. Comparison of variations of HbA_{1c} for each individual during booklet period (booklet) and during telematic period (telematic). *Bars*, means ± SE. $P = 0.05$ was significant.

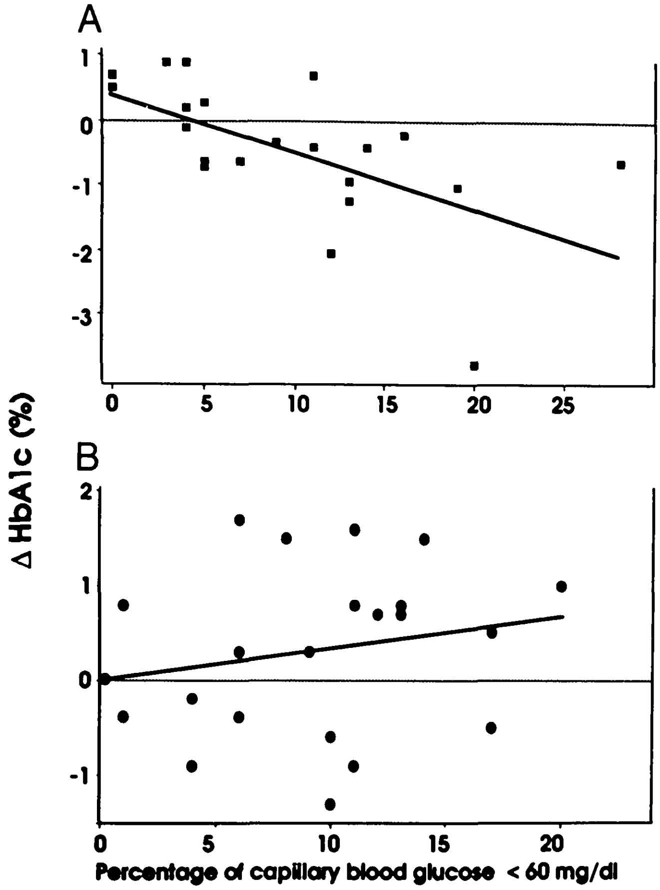

FIG. 4. Correlations between changes in HbA_{1c} and percentage of recorded low capillary blood glucose (<60 mg/dl, i.e., <3.3 mM) during telematic period (*A*; $r = -0.714$, $P = 0.0014$) and booklet period (*B*; $r = 0.144$, $P = 0.52$).

0.714, $P = 0.0014$, Spearman's rank test) but not during the booklet period ($r = 0.144$, $P = 0.52$), as shown in Fig. 4.

Table 2 shows the answers made by the diabetic patients to the questionnaire given at completion of the study. Of 21 patients who completed the study, 17 wanted to remain on the telematic system. However, all had used their booklets to record intercurrent events and insulin adjustments during the telematic phase. Patients and physicians suggested use of a telematic transmission of values that were faster than the one used for this study and a telematic recording of day-to-day insulin dosages and intercurrent events. Such improvements are in progress.

CONCLUSIONS

This study shows that computerized SMBG can be beneficial for IDDM patients when transmitted by telematic means. Although metabolic control was improved only slightly during the telematic period, patients liked the telematic network. Technological facilities can be further developed to offer a telematic alternative to the booklets used customarily by diabetic patients. The positive results we obtained were probably due to an improved feedback of SMBG analysis, which facilitates a better communication between patients and physicians.

The feasibility of this telematic network was good, and patients found it easy to manipulate. Programs and adaptors used to connect memory-reflectance meters to the telephone network were prototypes specially designed for this study. This explains why the transmission speed was slow, a limitation that can be improved if this telematic tool is used on a large scale. The Minitel network seems easier to handle and cheaper than a personal microcomputer for most of the population. Technical improvements are in progress to extend services offered to patients and physicians by the Minitel network.

A decline in HbA_{1c} was observed during the telematic period, which was not counterbalanced by weight gain or increased insulin dosages, suggesting this improve-

TABLE 2
Summary of answers made on questionnaire by diabetic patients at completion of study

	Telematic (%)	Booklet (%)	No opinion (%)
Requires more frequent fingersticking	50	14	36
More time consuming	64	27	9
Easier to modify insulin dosages	68	18	14
Simpler	59	32	9
More useful	86	9	5
More enjoyable	91	5	4
Overall preferred	82	13	5

For each question, patients had to choose one type of self-monitoring of blood glucose or that they had no opinion.

ment could be due to the telematic tool. The HbA_{1c} decline was small, because patients enrolled in this study were few and were well controlled (mean HbA_{1c} 6.7% at entry into the study). Hence, these results require confirmation by long-term follow-up studies with numerous patients, but they support the idea that transmission of computerized SMBG analysis with telematic means can help to improve diabetic control.

The discrepancy between glucose profiles and HbA_{1c} may have been explained by differences in SMBG recordings during the two periods. The correlation found between HbA_{1c} changes and recorded hypoglycemic episodes during the telematic period but not during the booklet period supports this hypothesis. This is in keeping with previous articles (4,5,7). Negative appreciations were contradictory, with the same frequency of fingersticks observed during the two types of SMBG (Table 1). This also supports the idea that values on booklets must be carefully interpreted.

These results were supported by preliminary reports from Zimmet et al. (7), who developed a telematic transmission of SMBG. However, the technical facilities of the Minitel network gave an immediate feedback of information to patients, which was an advantage compared with the system used by Zimmet et al. In this study, insulin treatment was not adapted automatically, because patients and physicians had to interpret SMBG on the basis of their own knowledge and experience. In contrast with computer-assisted insulin treatment, this system remained an open-loop circuit.

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