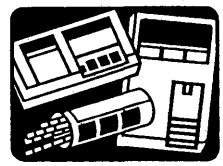
Technical Section



The Evaluation of a Pocket Computer as an Aid to Insulin Dose Determination by Patients

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A small and inexpensive computer was programmed to assist patients in making decisions regarding insulin delivery using constant subcutaneous infusion systems. Insulin dosage was based on gender, pre- and postprandial blood glucose, between-meal blood glucose, patient weight, time of day, and when appropriate, the carbohydrate content of food ingested. The system was self-adjusting based on postprandial and fasting blood glucose levels. A developmental phase in which the computer program was refined was undertaken with five highly trained type I patients using an insulin infusion pump. Then, based on the suggestions made by these patients, a final program was used by these same five patients for 1 mo. Computer-assisted insulin delivery resulted in lower mean blood glucose (162 versus 130 mg/dl) and hemoglobin A_{1c} (7.2% versus 5.8%) values when compared with precomputer values. In addition, there was a significant increase in the frequency of blood glucose testing during the computer-assisted periods in that patients monitored their blood glucose 4.9 times per day during the physician-alone period whereas a mean of 7.5 glucose tests were performed during the computer-assisted periods. Patient response to the concept was overwhelmingly favorable. These studies demonstrate that computer-assisted insulin-delivery decision making is feasible, acceptable to patients already accustomed to pump use, safe, effective, and may provide a savings in terms of professional time. DIABETES CARE 1985; 8:172–76.

The goal of achieving physiologic ranges of blood glucose in patients with diabetes mellitus is closer since the advent of several technologies. Self-monitoring of blood glucose systems and improved methods of insulin delivery are now available to patients and are widely employed.[1,2]

It has been estimated that optimum teaching of the skills and tools required to establish relatively physiologic blood glucose levels requires about 40 h of professional input.[3] Insulin-delivery decisions are especially problematic since there are multiple changing variables that must be considered with each insulin dose.[1] A program for optimal insulin delivery may require many variables to be entered before a dose of insulin can be recommended. These variables include: (1) the metabolic status of the patient (growing, pregnant, postmenopausal); (2) the activity level of the patient; (3) the present body weight and composition; (4) gender; (5) blood glucose before the meal; (6) carbohydrate content of the meal to be ingested; (7) timing of the insulin peak to coincide with the postprandial glucose peak; and (8) time of day.

An ideal computer would know its owner (gender, weight and body composition, metabolic status, insulin, and food time lags). Then when the owner wanted to eat, he or she would enter time of day, present blood glucose, and the meal plan, such as 12 noon, 50 mg/dl, PIZZA.

At present, computers with sufficient memory to deal with all the variables are expensive and complicated. A small, inexpensive computer was programmed to include important variables in insulin delivery and to be self-adjusting based on user input. This article describes the developmental phase of the computer program and documents (1) the safety of patient use of computer-assisted decision making for insulin delivery, (2) the effect of computer use on patient performance, and (3) patient acceptance of such a concept.

MATERIALS AND METHODS

Phase I: Development of Program

Initially, published algorithms[4] were used as the basis for the program. The first patient to help refine the program was a diabetologist, who used a pump for insulin infusion. Based on her suggestions, the programmer incorporated certain

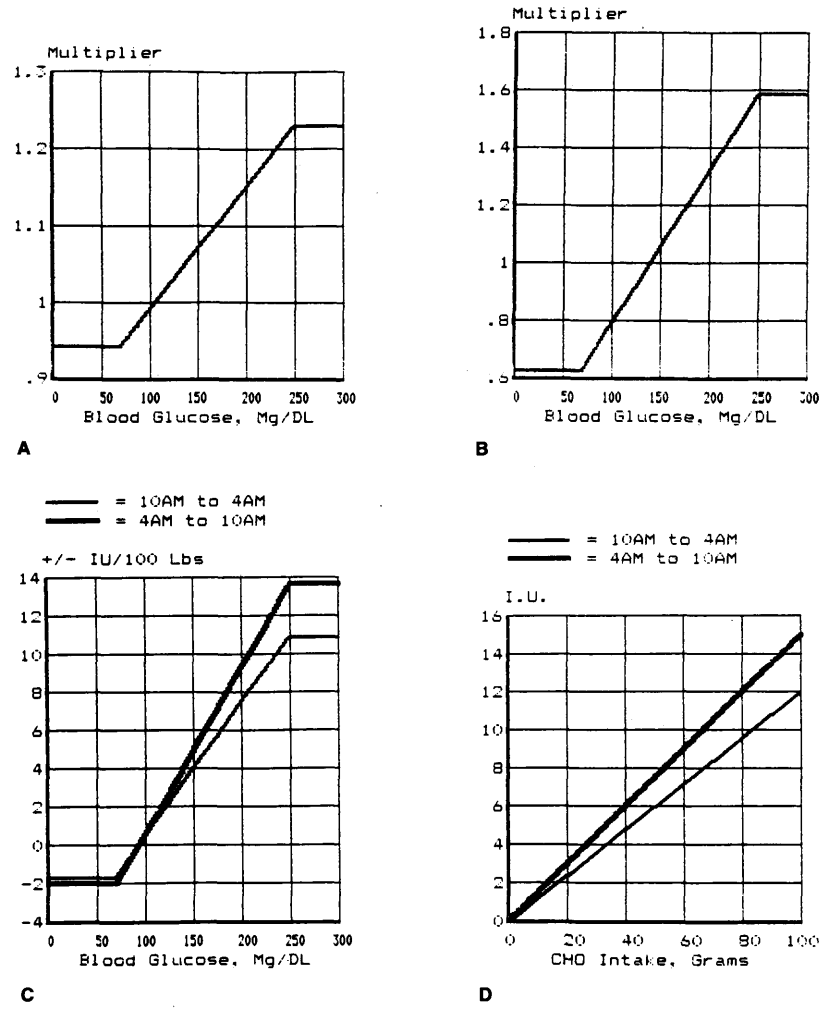

FIG. 1. (A) Basal adjustment multiplier; (B) postprandial bolus adjustment multiplier; (C) preprandial blood glucose normalization; (D) initial CHO/insulin ratio for female patients.

changes. Four additional pump patients who were graduates of a comprehensive diabetes education course designed to achieve and maintain normoglycemia using an insulin pump were chosen because of their records of excellence. These patients made additional suggestions. Thus, the final program was a result of the continued interaction between the programmer and computer users. Three brands of pumps were used in the study (three CPI 9200s, Cardiac Pacemakers, Inc., St. Paul, Minnesota; and one AS6C and one AS6MP, AutoSyringe, Division of Travenol, Chicago, Illinois).

Phase II: Data Collection

Prior to the month in which the final computer program was used by these same five patients, a period of 30 days without the computer was studied. All patients were asked to perform six blood glucose determinations a day and chart these blood glucose values in a diary. At the end of this 30-day period, the glucose diaries were collected, blood was drawn for glycosylated hemoglobin levels, and the finalized computer program was explained. Patients were seen again 1 mo later when the computers were collected and blood for repeat glycosylated hemoglobin levels was drawn.

Hemoglobin A_{1c} stable fraction was measured by high-performance liquid chromatography as described previously.[5] Inter- and intraassay coefficients of variation remained under 3% during the trial.

A small portable computer (Radio Shack TRS-80 PC-1) was chosen for programming because of several features. The size is convenient (175 × 70 × 15 mm) and there are adequate input/output display and memory capabilities, as well as CMOS battery backup so that information is retained during idle periods. There are a number of similar units available, all of which retail for under $100.

The computer program converted previously described[6,7] rules of insulin adjustment into continuous linear equations for all variables. The most significant relationships are described in Figure 1(A)–(D). If at any time the between-meal blood glucose was <70 mg/dl, the user was instructed to ingest 10 g of carbohydrate by the computer. Example supplemental boluses are as follows: if between 10 a.m. and 4

TABLE 1
Radio Shack TRS-80 PC-1 program: type I diabetic patients on CSII

```
1: GOTO 10
2: GOTO 50
3: GOTO 200
4: GOTO 250
5: GOTO 800
10: PAUSE "CSII PGM 9/83":INPUT"YOUR INITIALS?:";I$:K=12.7:
    INPUT"MALE OR FEMALE?(M/F)";J$:S=0
15: IF J$="F" LET K=11.34
20: INPUT"YOUR WEIGHT,LBS.="; C
25: INPUT"10AM-4AM BASAL=?";X:INPUT "4AM-10AM
    BASAL=?";Z:GOTO 140
50: PRINT"MEALTIME BOLUS PLAN"
55: GOSUB 670
60: GOSUB 640
65: Q=D
70: INPUT"WANT BASAL CHECK?(Y/N)";Y$
75: IF Y$="Y" THEN 400
80: INPUT "GRAMS CARBO.?:";F
85: IF F=0 THEN 140
90: INPUT "CALORIES THIS MEAL?:";G
95: M=M+F:P=P+G
100: IF D<70 LET D=70
105: IF D>250 LET D=250
110: L=.005143*D-.48
115: IF S=0 LET S=1
120: N=INT(100*S*F*B/K+10*L*B*C+.5)/10
125: IF N<0 LET N=0
130: PRINT"MEALTIME BOLUS=";N
135: IF D=93.33 GOTO 80
140: PAUSE"END":END
200: PRINT"NEXT BOLUS ADJ."
205: GOSUB 640
210: IF D<70 LET D=70
215: IF D>250 LET D=250
220: S=.2533+D/187:GOTO 140
250: PRINT"BETWEEN MEAL CHECK"
255: GOSUB 670
260: GOSUB 640
265: IF D<70 GOTO 300
270: IF D<111 GOTO 295
275: IF D>250 LET D=250
280: T=.001*D-.081
285: V=INT(10*T*B*C+.5)/10
290: PRINT"TAKE BOLUS NOW!!=";V:GOTO 140
295: PRINT"NO BOLUS NECESSARY":GOTO 140
300: BEEP 9:PRINT"EAT 10 GM. CARBO. NOW!!":M=M+10:
    P=P+40:GOTO 140
400: IF Q<70 LET Q=70
405: IF Q>250 LET Q=250
410: W=.833+.00159*Q
415: IF A$="N" GOTO 425
420: X=INT(10*X*W+.5)/10:PRINT"10AM-4AM BASAL
    DOSE=";X:GOTO 80
425: Z=INT(10*Z*W+.5)/10:PRINT"4AM-10AM BASAL
    DOSE=";Z:GOTO 80
640: INPUT"PRESENT BLOOD SUGAR=";D:IF D=0 THEN 700
645: H=H+1:R=R+D:E=INT(R/H+.5)
650: RETURN
670: B=.136:INPUT"10AM-4AM?(Y/N)";A$
675: IF A$="N" LET B=.17
680: RETURN
700: D=93.33:GOTO 80
800: PAUSE I$;",S PLAN":PRINT"AVE.B.S.=";E:" TESTS=";H
805: PRINT"RUNNING CHO,GM.=";M:PRINT"RUNNING
    CAL.=";P
810: IF M=0 THEN 845
815: U=INT(400*M/P+.5)
820: PRINT"RUNNING %CHO=";U
825: F=0:G=0
830: INPUT"RESET CHO-CAL.?(Y/N)";U$
835: IF U$="N" THEN 850
840: PAUSE"RESET"
845: M=0:P=0
850: IF E=0 THEN 140
855: INPUT"RESET B.S. DATA?(Y/N):";O$
860: If O$="N" THEN 140
865: E=0:H=0:R=0:PAUSE"RESET-END":END
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a.m. the blood glucose between meals was 110 mg/dl, insulin was given as a bolus = 0.009 × body weight (kg), and if the blood glucose was 140 mg/dl, insulin was given = 0.018 × body weight (kg). If between 4 a.m. and 10 a.m. the blood glucose was 100 mg/dl, insulin was given = 0.011 × body weight (kg), and if the blood glucose was 140 mg/dl, insulin was given = 0.222 × body weight (kg). The computer interpolates for all intermediate blood glucose values.

During the physician-assisted period, insulin adjustment was by 2–4-U increments as described previously.[1,2] In the computer, these stepped relationships were reduced to continuous equations to more properly describe the physiologic continuum of insulin effect. To avoid major excursions in therapeutic adjustments, limits of 70 and 250 mg/dl were imposed upon these equations. That is, all values below 70 were treated as 70 and all values over 250 were treated as 250.

Entry Points of the Program

The final Basic language program is shown in Table 1. In use, the patient "runs" the programs by typing in the letter r (for run), followed by the numbers 1–5 depending on which program routine is desired. The computer responds by displaying easily understood messages and questions. The completion of each routine is signified with an "end" message. The entry points for the five possible routine are described below.

Entry 1: patient data base input. This routine requires the input of the patient name or initials (up to seven characters), weight (in pounds), gender, the prescribed basal rate of the patient for the hours 10 a.m.–4 a.m., and the prescribed 4 a.m.–10 a.m. basal rate (as U/24 h or U/h). This routine has no output information, and need only be run upon a significant change in body weight or metabolic status. In this program, no attempt was made to quantitate exercise as a variable. The authors have observed an approximate 10%

difference in the bolus requirements of men and women, and thus gender was chosen as a variable.

Entry 2: mealtime bolus plan input. This routine includes a request for the time of day, preprandial blood glucose, opportunity for a basal rate check, carbohydrate content of the meal (in grams), and the caloric content of the meal. This routine can either be used for the entire meal or used repeatedly throughout the meal if the patient prefers to administer insulin on a course-by-course basis. The output includes the revised basal rate (if requested) and the mealtime bolus (insulin units).

Entry 3: mealtime bolus adjustment. This routine uses the last meal's postprandial blood glucose level to adjust and continually refine future preprandial bolus recommendations. This self-adjusting feature allows the computer to learn from the present blood glucose excursion a better insulin dosage specifically for the patient's carbohydrate and insulin need and the patient's tendencies to under- or overestimate carbohydrate ingested. Thus, over time, an insulin dosage is derived that is individualized to each patient.

Entry 4: between-meal blood glucose measurements. This routine recommends between-meal supplemental insulin or snacks as necessary to reestablish normoglycemia. Based on the blood glucose level, the computer suggests the amount of insulin necessary to lower blood glucose to a level of 90–100. This suggested action is for blood glucose levels above 100 mg/dl and increases linearly to 250 mg/dl. A snack of 10 g of carbohydrate is suggested for a blood glucose of <70 mg/dl.

Entry 5: the patient's average blood glucose and food record. This section of the routine is an ongoing average of patient input into the computer. The routine recalls a memory function to present ongoing average blood glucose, total number of blood glucose tests performed, and the continuing carbohydrate intake in relationship to caloric intake expressed as total grams and as a percent of total ingested calories. This feature is valuable to both the patient and the health care provider in that it provides the patient information on glycemic control, which serves as a positive reinforcement to continued computer use, provides information to the health care team, and confirms compliance of the patient.

RESULTS

The initial program had a number of features that were not well received by patients, including (1) audible tones before every output message, (2) patient identification before every output message, (3) opportunity to redo any meal plan input that deviated by more than 10% from a target carbohydrate/calorie ratio, (4) running blood sugar, carbohydrate, and calorie data with each input, and (5) editorial commentary such as "LOOKING GOOD" for normal blood glucose values, and "HI CARBO," "LO CARBO," and "GOOD MEAL PLAN."

The mean blood glucose dropped from 162 mg/dl at the beginning of the data collection phase to 129 mg/dl at the end of this phase, with a parallel drop in hemoglobin A_{1c} values from 7.2% to 5.8%.

The frequency of self-blood-glucose testing increased from 4.9 at the beginning of the data collection phase to 7.5 during computer use. There were no episodes of hypoglycemia (BS < 70) during which the patients could not adequately treat themselves with the suggested carbohydrate snack.

DISCUSSION

The present study demonstrates the feasibility and safety of computer-assisted management of patients with type I diabetes mellitus who use pump insulin delivery systems. The results in terms of glycemic control using the computer showed improvement in terms of frequency of blood glucose measurements, average blood glucose levels, and glycosylated hemoglobin levels.

The frequency of self-monitoring of blood glucose increased during computer usage. While some of this increase is probably attributable to the novelty of the computer, it also became apparent that motivation for self-monitoring increased with the perception of computer interaction and that the results are both immediately and beneficially useful. All patients believed that the computer aided the learning process, and were particularly interested in the ongoing average blood glucose and dietary data, which provided a positive reinforcement for the effort required.

While it must be kept in mind that the five patients in this study are perhaps more skilled in the care of diabetes, the computer did not contribute to deterioration of glucose control but, in fact, glycemic levels improved. There were no untoward consequences of computer use. Whether or not computer-assisted insulin dosing is applicable and safe to the general population of insulin-requiring diabetic patients remains to be verified.

One of the beneficial findings in this group of five patients was behavior modification. The general error made by this group before computer use was to underestimate the insulin doses required for a large carbohydrate meal. Because the computer has no bias about dietary indiscretion, the appropriate dose of insulin is recommended.

Until the advent of new technologies that convert blood glucose values into automated insulin delivery systems, the use of pocket computers to assist in insulin dosage decisions appears to be a logical step. Within the framework of this study, pocket computers are safe, effective in terms of achieving target glycemic levels, and an acceptable methodology to the patient. Further studies are warranted to test whether these technologies facilitate patient education, decrease professional time requirements, or improve general patient compliance.

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