

# Modem Transmission of Glucose Values Reduces the Costs and Need for Clinic Visits

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**OBJECTIVE** — To determine whether modem technology allows for effective management of type 1 diabetes when used in lieu of a clinic visit.

**RESEARCH DESIGN AND METHODS** — A total of 70 adolescent patients with diabetes were prospectively randomized to either a control group or a modem group. Control group patients continued the standard of care of quarterly clinic visits, and modem group patients were instructed to transmit blood glucose data every 2 weeks for 6 months instead of a usual quarterly clinic visit. Health care providers analyzed the data received by modem and contacted patients to discuss diabetes treatment changes. GHbA<sub>1c</sub> levels were determined at 0 and 6 months, and the number of high and low blood glucose levels and adverse events were tracked. Clinic visit costs, patient expenses, and health care provider times were tracked for cost analysis for both groups.

**RESULTS** — A total of 63 patients (33 control, 30 modem) completed the 6-month study. The GHbA<sub>1c</sub> values significantly decreased in both groups, with no statistically significant difference between groups ( $P = 0.96$ ). The occurrence of mild-to-moderate hypoglycemic events were similar in the two groups, and there were no severe hypoglycemic events. The average cost of care for a clinic visit was \$305.00, whereas the cost for 6 months of modem transmission was \$163.00.

**CONCLUSIONS** — This study shows that electronic transmission of blood glucose levels and other diabetes data every 2 weeks—in lieu of a clinic visit—results in a similar level of glucose control and incidence of acute diabetes complications when compared with current standard care.

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Effective self-management of type 1 diabetes is essential to the prevention of acute complications and the minimization of long-term complications. Most diabetes programs, including the study clinic and the American Diabetes Association, recommend clinic visits for patients with type 1 diabetes every 3 months (1). However, because of a current

shortage of pediatric diabetologists, the case loads have increased, and clinic visits every 3 months are not always possible for adolescents with diabetes. The Diabetes Control and Complications Trial (DCCT) stressed the importance of intensive diabetes management and the lowering of GHbA<sub>1c</sub> values to prevent long-term microvascular diabetes complications. The

challenge then is to find alternative ways to monitor glucose control within the context of an overstressed diabetes care system. Streamlining diabetes care while maintaining quality will be an increasing challenge as the number of people with diabetes grows. One alternative may be frequent contact using electronic data submission via modem technology as an expanded approach to the outpatient management of patients with type 1 diabetes.

The purpose of this study was to evaluate the effect of transmitting blood glucose data every 2 weeks using the Acculink modem (Roche Diagnostic, Indianapolis, IN) and omitting a 3-month clinic visit, compared with clinic visits every 3 months, in an adolescent population with type 1 diabetes.

## RESEARCH DESIGN AND METHODS

### Participants

A total of 70 adolescents aged 15–20 years, diagnosed with type 1 diabetes for at least 1 year, were randomized to one of two groups in this prospective randomized clinical study. Volunteers were recruited from a Denver, Colorado, pediatric and young adult diabetes clinic.

Male and female subjects aged 15–20 years who were diagnosed with type 1 diabetes for at least 1 year and with an GHbA<sub>1c</sub> value of 7.0–13.0% and a hematocrit of 20–55% at screening were included. Patients were included only if they took at least two insulin injections per day or used pump therapy and were willing to perform at least two blood glucose tests per day. All patients, and parents if the patient was <18 years old, signed a consent form approved by the Colorado Multiple Institutional Review Board.

Patients were excluded if they had any significant diseases other than diabetes or plans to become pregnant during the next 6 months. Taking illegal drugs, planning surgery in the next 6 months, or being a ward of the state were also exclu-

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**Abbreviations:** DCCT, Diabetes Control and Complications Trial.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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See accompanying editorial, p. 1626.

sion criteria. No one was excluded on the basis of ethnicity or sex.

**Procedures**

The control group had three clinic visits during the 6-month period at 0, 3, and 6 months, with the option to telephone or fax blood glucose results to the clinic as desired by the patient or recommended by the physician. The modem group had two clinic visits, at 0 and 6 months, and electronically transmitted blood glucose information to the clinic approximately every 2 weeks during the 6-month period. A health care provider, either a registered nurse (for 33 patients) or a doctor (for 2 patients), was assigned to each of the 35 modem patients for the 6-month period. The health care provider reviewed each transmission and called the patient to both discuss the information transmitted and make treatment changes as needed.

GHbA<sub>1c</sub> values were measured at 0 and 6 months for all patients, using the DCA-2000 meter (Bayer Laboratories, Elkhart, IN). The control group also had GHbA<sub>1c</sub> determinations at 3 months, but the results were blinded to the care providers. The accuracy of the use of the DCA-2000 instrument had been documented previously (2). All patients were asked to check their blood glucose levels as often as they needed, but at least two times per day. An Accu-Chek Complete meter (Roche Diagnostic) and test strips were provided to all patients at no cost for the 6-month study. The modem group also received free modems.

Blood glucose testing frequency was determined from the meter downloads for each patient during each clinic visit. The occurrence of diabetes-related incidents was reported by the patients, whereas the incidence of mild-to-moderate hypoglycemia was determined from the patient meter downloads during each clinic visit. Severe hypoglycemic episodes were defined as per the DCCT (3). Downloaded data were analyzed to detect the number of high ( $\geq 300$  mg/dl [ $\geq 16.6$  mmol/l]) and low ( $< 60$  mg/dl [ $< 3.9$  mmol/l]) glucose levels as well as the number of insulin dose changes and carbohydrate, exercise, and event marker entries. The number of "Feel Hypo" and "Feel High Sugar" event markers were also counted. The sum totals of each category were divided by the number of weeks in the patient's download to obtain average

**Table 1—Demographics and GHbA<sub>1c</sub> values**

Group	n	Sex (M/F)	Age* (years)	Duration of diabetes* (years)	GHbA <sub>1c</sub>	
					Initial	Final (6 months)
Control	33	16/17	17.2 ± 1.5	7.4 ± 3.1	8.9 ± 1.1	8.6 ± 1.7
Acculink	30	14/16	17.4 ± 1.7	8.4 ± 4.6	9.0 ± 1.2	8.6 ± 1.2

Data are means ± SD. \*Results represent the mean ± 1 SD. There were no statistically significant differences ( $P > 0.05$ ) between the control and modem groups.

numbers of entries for each category per week.

A cost analysis was performed to determine the expense of a clinic visit versus the use of the Acculink Modem for the 6-month period. Clinic visit costs were based on the cost to the patient/family or insurance company for the clinic visit plus additional patient costs such as parking, mileage, meals, hotel stay, and babysitting. At each clinic visit, patients and their families were asked to complete an expense log that itemized these expenses.

For the modem group, transmission review and telephone follow-up, including calls that were not answered or picked up, were timed, and the cost of each transmission was calculated using health care professional salaries broken down into hourly wages (registered nurse average wage = \$25.00/h, and doctor average wage = \$50.00/h) plus 51% institutional overhead. Patient/family time was analyzed at a cost of \$15.00/h. Costs of the modem and a designated computer (plus analog time) to receive data, amortized over an average lifespan of 3 years with usage of 6 months, were included as a cost for the modem group.

A Patient Satisfaction Questionnaire was administered at 6 months to each patient. The responses to the questions concerning overall satisfaction with the diabetes care received during the clinical study were averaged to determine the overall satisfaction for each group.

**Data analysis**

Diabetes parameters evaluated for the two groups during the study included GHbA<sub>1c</sub> values (including between-group and within-group comparisons), blood glucose testing and data transmission compliance, the incidence of hypoglycemia and diabetic ketoacidosis, the cost of care, and the degree of patient satisfaction. Student's *t* test and the SAS/STAT statistical program were used for all

statistical analyses (4). Data from completed patients were analyzed, rather than "intent-to-treat," because intent-to-treat would have falsely lowered the costs for the modem group. Because follow-up data were not available for any of the two control or five modem group discontinued patients, the "last observation carried forward" was not applicable for statistical analysis.

**RESULTS**

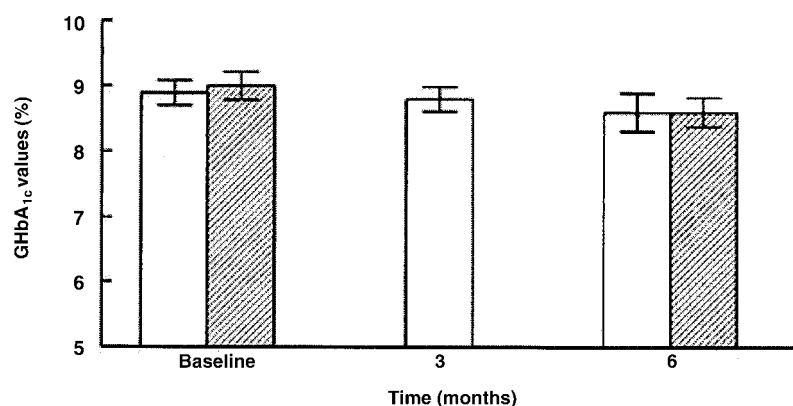
**Patient population**

A total of 63 patients (30 male and 33 female subjects) completed the study. All patients were Caucasian and non-Hispanic. Seven patients were discontinued from the study (five modem and two control subjects) because of noncompliance with the protocol, such as not transmitting glucose data (five patients) and inability to attend the 3-month clinic visit (two patients). There was no significant difference in the discontinuation rate between the two groups ( $P = 0.232$ ,  $\chi^2$  test). The mean age and duration of diabetes were comparable for the two groups (Table 1).

**Degree of glycemic control**

The mean baseline GHbA<sub>1c</sub> values were  $8.9 \pm 1.1$  and  $9.0 \pm 1.2\%$  for the control and modem groups, respectively ( $P = 0.89$ , *t* test). There were no differences in the mean GHbA<sub>1c</sub> values at the 6-month visit between the two groups ( $P = 0.96$ , *t* test), with a mean GHbA<sub>1c</sub> value of  $8.6 \pm 1.2$  and  $8.6 \pm 1.7\%$  for the control and modem groups, respectively (Fig. 1). There were also no differences in subgroup analysis by GHbA<sub>1c</sub>. We found that 10 of 13 subjects in the control group and 9 of 13 subjects in the modem group who initially had GHbA<sub>1c</sub> values  $\geq 9.0\%$  decreased their 6-month value by  $> 0.5\%$ . Testing compliance was similar in the two groups. Patients in the control group

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**Figure 1**—Mean GHbA<sub>1c</sub> values at 0 and 6 months in the control (□) and modem (▨) groups. Differences were not statistically significant ( $P > 0.05$ ) between groups or from initial to final values.

tested their blood glucose an average of 3.0 times per day, whereas the modem group tested an average of 2.9 times per day ( $P = 0.91$ ,  $t$  test).

#### Cost of care

The difference in cost of care between the two groups was significant ( $P < 0.001$ ,  $t$  test). The average total time spent per clinic visit was 95 min (range 60–128). The average cost of a clinic visit was \$246 (235–310). If additional costs (average \$59) such as mileage, parking, meals, hotel stays, and babysitting were included, the average cost of a clinic visit increased to \$305 (245–810). The costs are summarized in Table 2. Additionally, the average number of school days missed for the 3-month clinic visit for the control group was 0.4 days per patient. Control group patient parents also missed an average of 0.5 days of work per clinic visit.

The average cost per patient in the modem group for the 6 months was \$163.00 (Table 2). The patients sent an average of 8.5 transmissions during the 6-month period, and health care providers spent an average of 9.5 min per transmission to review the data and discuss the treatment changes with the patient (at a cost of \$50.00) (Table 2). The average life of a modem is ~3 years. The cost of the modem and cable is \$101.95. It was amortized over 3 years with 6 months of usage (\$17.00 per patient). The cost of training providers and teaching patients to use the modem was estimated at \$35.00 for each (inclusive of institutional overhead). The cost of the designated computer (plus analog line) was estimated at \$10.00 per patient (Table 2).

The patient costs included training to use the modem, talking to the care provider, entering data into their meter, and transmitting data, for a total of \$48.00 (Table 2).

The patients in the modem group in fact sent fewer than the anticipated number of transmittals (an average of 8.5 vs. an anticipated 12) over the 6-month period. Even if the patients had sent the projected 12 transmittals, the use of the modem would still have been more eco-

nomical, costing a theoretical \$173.00 per patient for the 6 months, compared with \$305 for a clinic visit.

#### Patient satisfaction

Both groups expressed high satisfaction with their overall diabetes care during the course of the clinical study, with no statistically significant difference between the groups ( $P = 0.81$ ). On a scale of 1–7, with 1 being the most favorable, the mean values were 2.2 and 2.6 for the control and modem groups, respectively, for overall satisfaction regarding diabetes care during the course of the study.

In terms of the use of the Accu-Chek Complete blood glucose monitor, the most frequently used additional features were those that recorded data about insulin injections (6.1 times/week) and carbohydrate intake (1.5 times/week). The modem group recorded more event markers (e.g. for exercise, fasting, after-meal levels, or illness) per week (11.5) than the control group (5.9).

#### Incidence of acute diabetes complications

The occurrence of diabetic ketoacidosis and hypoglycemic events were similar for the two groups. One patient in each group

**Table 2**—Summary of costs of care

Group	U.S. dollars
Modem group	
Modem cost*	17
Modem (and meter) training of RN and for RN to teach each patient/parent to use	35
Provider time for downloading data and phone conversations (9.5 min each × 8.5 transmissions × \$37.00/h [including overhead])	50
Patient (±parent) time in hours (estimated at \$15.00/h)	
Training	0.5
Talking to care provider	1.4
Entering data (food, exercise, lows, etc.)†	1.1
Transmitting data (max = 1.5 min each)	0.2
Phone expense (family)	48
Designated computer (used for 6 months and amortized over 3 years) and analog line	10
Total	163.00
Control group	
3-month clinic visit	246 (235–310)
Additional costs (parking, meals, mileage, hotels, etc.)	59 (10–505)
Total	305.00

Data are \$ and \$ (range). \*The total cost of the modem (\$101.95) with use for 6 months was amortized over 3 years; †the time of entering data by the patients was estimated based on the number of entries received (22/patient × 3 min/day = 66 min/180 days). RN, registered nurse.

had several episodes of diabetic ketoacidosis (three episodes for the control group patient and two for the modem group patient). Each group also had one patient who had an episode of mild diabetic ketonuria not requiring hospitalization. Mild-to-moderate hypoglycemia occurred an average of 1.4 times/week in the control group and 1.5 times/week in the modem group ( $P = 0.71$ ,  $t$  test). There were no episodes of severe hypoglycemia in either group.

**CONCLUSIONS**— The use of modem technology for biweekly communication of blood glucose results and other diabetes-related information to a health care provider was shown to be a viable alternative to clinic visits every 3 months for an adolescent population with type 1 diabetes. The glycemic control and the incidence of acute diabetes-related complications were comparable between the two groups, even though the modem group did not have a 3-month clinic visit. The cost analysis for biweekly transmission of blood glucose data, compared with the standard care of clinic visits every 3 months, indicated that using the Acculink modem to transmit blood glucose data over a 6-month period is more cost-effective than the standard of care. Also, the modem group missed fewer days of school and their parents missed fewer days of work as a result of omitting the 3-month visit. Part of the reduction in cost was attributable to most modem transmissions being handled by nurses, in comparison to physician costs included in the cost of a clinic visit. The reduction in overhead costs was also a factor. The savings of clinic space and of physician time were considered a benefit for the care providers.

Electronic data submission has previously been shown to be successfully incorporated into the outpatient care of pediatric patients with type 1 diabetes (5). Marrero et al. (5) found no significant between-group differences for metabolic control, rates of hospitalization or emergency room visits, psychological status, general family functioning, quality of life, or parent-child responsibility between youth using a telecommunication system and control subjects. Although they did not observe any benefits of using the system in terms of glycemic control, others have reported improvement (6–8). Marrero et al. did not address cost-

effectiveness or the extent to which such systems could be used to reduce the frequency of clinic visits, but they noted the need for these assessments (as now reported in this study).

The degree of patient satisfaction with the care received was similar in the two groups, with both groups indicating high satisfaction with their health care during participation in the study. The patient satisfaction and patient care results might have been different among patients with comorbid illnesses as well as among newly diagnosed patients. Frequent clinic contact may be more important for patients and families initiating self-care and diabetes education. These groups of patients were not studied in this protocol and may be the subject of a future study.

All patients seen at the clinic receive computer-printed take-home directions to fax blood glucose results or other information as often as they wish. This rarely occurred with the control group patients, less than once every 3 months per family, and was thus not included in the cost analysis. The general experience at the clinic is that patients or members of their family usually fax blood glucose values regularly during the first 1 or 2 years after diagnosis. However, older children and teenagers who have had diabetes for 7–8 years, as in this study, are usually responsible for their own diabetes care, and the recording and faxing of glucose values is not a priority for them. The use of the Acculink modem provided a viable technology to alter this behavior.

Both the control and the modem groups showed a similar decline in their  $\text{GHbA}_{1c}$  levels over the 6 study months. Presumably, this was a combination of the “study effect” as well as all participants agreeing to do at least two blood glucose tests per day. Accu-Chek Complete meters and Accu-Chek Comfort Curve test strips were provided to the patients in both groups, and this may have also helped increase the testing frequency. On average, patients in the control group tested 3.0 times/day and patients in the modem group tested an average of 2.9 times/day. The fact that control patients received free supplies might have affected the results.

As the population of youth with type 1 and type 2 diabetes has increased over recent years (9,10), the number of diabetes care providers has not similarly increased. There are currently  $>100$

positions advertised on the Lawson-Wilkins endocrine website for pediatric diabetes care physicians. Applicants for pediatric endocrine diabetes training have shown a steady decline over the past decade. Each year,  $\sim 15$  physicians complete training and remain in the U.S. to practice. Similarly, clinic space has not increased and, even if more care providers were available, many clinics would not have the space to see more patients. Use of data transmission as described in this study could help to solve both physician and space limitations. Obviously, not all families would benefit from reducing clinic visits, and families with noncompliance or psychological issues or who are in need of further education should not miss a clinic visit.

A major factor in the use of electronic data submission via modem technology relates to payment of the health care providers for the biweekly communications. The medical insurance industry would need to agree to work out a method of reimbursing the health care team. This might be done by reimbursing costs on a per-patient per-year basis or reimbursing for each transmission. This clinical study documented that the cost of electronic data transmission was less expensive than routine clinic visits. However, there is a potential of worsening of compliance, and thus glucose control, if this were initiated as standard clinical practice. In most circumstances, annual eye and kidney exams will not be missed because of a missed 3-month visit, since these tests would be completed at the 6-month visit.

In summary, this prospective study examined the use of transmission via the Acculink modem of blood glucose and other diabetes-related data on a biweekly basis in lieu of a clinic visit. Modem technology is appropriate for use in an adolescent and young-adult population with type 1 diabetes and would be most applicable for those who travel great distances to reach the clinic and for those who do not need the psychological support of the clinic visit. A challenge for health care providers in implementing this technology will be convincing health insurance companies to pay for the modem/telemedical care.

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