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Use of the DirecNet Applied Treatment Algorithm (DATA) for Diabetes Management with a Real-Time Continuous Glucose Monitor (the FreeStyle Navigator)

Diabetes Research in Children Network (DirecNet) Study Group*

Abstract

Background—There are no published guidelines for use of real-time continuous glucose monitoring data by a patient; we therefore developed the DirecNet Applied Treatment Algorithm (DATA). The DATA provides algorithms for making diabetes management decisions using glucose values: a) in real time which include the direction and rate of change of glucose levels, and b) retrospectively based on downloaded sensor data.

Objective—To evaluate the use and effectiveness of the DATA in children with diabetes using a real-time continuous glucose sensor (the FreeStyle Navigator).

Subjects—30 children and adolescents (mean ± SD age = 11.2 ± 4.1 years) receiving insulin pump therapy.

Methods—Subjects were instructed on use of the DATA and were asked to download their Navigator weekly to review glucose patterns. An Algorithm Satisfaction Questionnaire was completed at 3, 7 and 13 weeks.

Results—At 13 weeks, all of the subjects and all but one parent thought that the DATA gave good, clear directions for insulin dosing, and thought the guidelines improved their post prandial glucose levels. In responding to alarms, 86% of patients used the DATA at least 50% of the time at 3 weeks, and 59% reported doing so at 13 weeks. Similar results were seen in using the DATA to adjust pre-meal bolus doses of insulin.

Conclusions—These results demonstrate the feasibility of implementing the DATA when real-time continuous glucose monitoring is initiated and support its use in future clinical trials of real-time continuous glucose monitoring.

Keywords

Type 1 Diabetes; Insulin Infusion Systems; Children; Blood Glucose

Introduction

Real-time continuous glucose monitors could revolutionize treatment of type 1 diabetes (T1D). The FDA has recently approved 3 such devices (the Medtronic Minimed Guardian REAL-Time, the Medtronic Minimed Paradigm REAL-Time 722 system, and the DexCom STS), and at least one other device (the Abbott Diabetes Care FreeStyle Navigator) may soon be approved. These devices provide patients with hundreds of glucose measurements each day and

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information regarding post-prandial and overnight glucose profiles that are not feasible with conventional self monitoring of blood glucose (SMBG).

For real-time continuous glucose monitoring to be effective, patients need to know how to utilize the information provided by the device. Since there are no published guidelines for the use of continuous glucose monitoring data, we developed the DirecNet Applied Treatment Algorithm (DATA). The DATA provides patients with algorithms for making insulin dose adjustments based on glucose values in real time that include the direction and rate of change of the glucose concentrations. The DATA also provides patients with guidelines on how to review downloaded data retrospectively to adjust their diabetes management based on pre- and post-prandial glucose targets and overnight readings.

The DATA was assessed in conjunction with a pilot and feasibility study of the FreeStyle Navigator® Continuous Glucose Monitoring System ("Navigator"; Abbott Diabetes Care, Alameda, CA) in 30 pediatric subjects. The primary goals of this pilot study were to determine if children would wear the sensor on a daily basis and to determine if there were any limitations on its use based on age of the patient or other clinical factors. In the pilot study (1) Navigator use averaged 136 hours of wear (107 hours of glucose values) per week and mean A1c dropped from 7.1% at baseline to 6.8% at 13 weeks (p=0.02). There were no severe hypoglycemic events. Herein the results of a questionnaire evaluating subject and parent satisfaction with the DATA are reported.

Methods

The study was conducted by the Diabetes Research in Children Network (DirecNet) Study Group at five clinical centers. A Data and Safety Monitoring Board and the Institutional Review Boards at each center approved the study protocol, consent form and assent form. A parent or guardian and each subject at least 7 years old gave written consent and assent, respectively.

The study protocol reported elsewhere (1) is briefly described below. The study consisted of an initial run-in period of approximately one week during which Navigator use was blinded to collect baseline glucose data, followed by a 24-hour inpatient stay in a clinical research center during which the accuracy of the Navigator was evaluated and parents and subjects were instructed on use of the Navigator and DATA, followed by home use of the Navigator for 3 months.

Thirty-three subjects were enrolled into the run-in phase. Three of the 33 (9%) withdrew during this phase because the sensor kept falling off (N=1), pain with use (N=1) or other family priorities (N=1). The remaining 30 subjects had an average age of 11.2 ± 4.1 years (range 4 to 17); 40% were female and 93% Caucasian. Mean duration of diabetes was 5.8 ± 3.0 years. Two (7%) subjects (age 4 and 11 years) dropped out of the study following the 7-week visit due to difficulty wearing the sensor and complaints of inaccuracy. The remaining 28 subjects completed the 13-week visit.

The DATA provided subjects and caregivers with written instructions on how to utilize the information from the Navigator. The specific instructions that were provided are included in the Appendix at end of this manuscript. There were two major components of the DATA: the first involves making adjustments to diabetes management using the real-time glucose readings, and the second involves the retrospective analysis of downloaded data. For real-time readings, the calculated pre-meal insulin bolus was adjusted up or down by either 10% or 20% based on the trend arrow on the Navigator indicating a positive or negative rate of glucose change (>1.0 mg/dl-min is indicated by a 45° up or down arrow, and >2.0 mg/dl-min is indicated by a 90° up or down arrow). Hypoglycemia alarms were to be verified with the FreeStyle meter and then treated with 15g carbohydrate (CHO) if the FreeStyle meter reading

was <70 mg/dl. Alarms for impending hypoglycemia were to be treated with 10g CHO. Hyperglycemia alarms more than 2 hours following a meal bolus were treated to a target glucose level specified by the DATA based on the subject's insulin sensitivity or correction factor (see Appendix).

In the second component of the DATA, sensor glucose data were downloaded and reviewed retrospectively once or twice a week by the subject and/or caregiver using the Navigator software. The day was divided into 2 to 3 hour time intervals. If a high percentage of glucose values were outside the target range specified by the DATA (customized to the subject and varied by time of day), the corresponding insulin basal rates or bolus doses were to be adjusted. For values consistently outside the target range within 3 hours of a meal, the bolus insulin dose was adjusted; for trends not within 3 hours of a meal, the basal rates were adjusted.

The Algorithm Satisfaction Questionnaire (developed by DirecNet investigators for this study to assess use of and satisfaction with the DATA) was completed at 3, 7 and 13 weeks by the primary caregivers and by subjects ≥ 9 years of age. The questionnaire consists of 6 questions that assess the frequency of use of the DATA for specific actions such as adjusting pre-meal insulin bolus dose (1=Never through 5=Always) and the perceived effect of each type of action on glucose level (1= Badly through 5 = Very Well). Additional questions evaluate respondents' satisfaction with selected aspects of the DATA (e.g. clarity, utility) by reporting their agreement with 6 statements (1=Strongly Disagree through 5=Strongly Agree). Higher item scores reflected more favorable ratings of the DATA in terms of frequency of use, effects on glycemic control and satisfaction with the guidelines.

Statistical Methods

The 30 subjects for this pilot study were a convenience sample not based on statistical principles. Changes in binary measures (diabetes management, questionnaire responses) over time were evaluated using McNemar's Test.

Results

At 3 weeks, 82% of the subjects and 96% of the parents thought that the DATA gave good and clear directions for insulin management (Table 1). At 13 weeks these numbers had decreased to 59% of the subjects and 73% of the parents. Even though the DATA often suggested insulin doses that differed from what they would have selected on their own, the effects on glucose levels were perceived as very favorable. Indeed, both parents and subjects agreed that using the guidelines helped them make good use of the Navigator readings.

In the first week of the study only 10% of subjects reported making changes to their carbohydrate to insulin ratios, but by the end of the study 25% of subjects reported adjusting their ratios (p=0.10). In the first week of the study 20% of subjects reported making changes to their basal insulin rate, and by the 13th week 32% of subjects reported making changes (p=0.32).

As the study progressed subjects and parents reported using the DATA less often (Table 2). For example, 68% of subjects reported using the DATA most of the time or always to adjust pre-meal bolus at 3 weeks compared with 41% of subjects at 13 weeks (p=0.03).

Discussion

Algorithms have been developed which use the information from fingerstick glucose levels to manage T1D with (2) and without (3,4) the assistance of a computer program. Algorithms have also been used to regulate intravenous insulin delivery in hospitalized intensive care unit

patients (5–10). There are no published reports, however, of using an algorithm for making diabetes management decisions using a real-time continuous glucose sensor in ambulatory, non-hospitalized patients. Patients initiating use of a real-time sensor need to have clear guidelines on how to utilize the trend and alarm information provided by these sensors, as well as instructions for making retrospective adjustments. For studies examining the efficacy and safety of glucose sensors, specified treatment guidelines are needed to fully interpret the outcomes of such investigations. The DirecNet Study Group developed the DATA to fill these unmet needs.

Real-time, continuous glucose monitoring using the Navigator provides patients with a glucose reading every minute and much more information about their blood glucose fluctuations than 3–4 discrete glucose measurements each day. This additional information could potentially result in information overload. In this study subjects did not become overwhelmed and instead felt the Navigator made it easier to make insulin dose adjustments and diabetes management decisions. Subjects and parents also reported that using the DATA assisted them in making insulin dose adjustments and thought the algorithm had a positive effect on their glucose values. Modest improvements in glycemic control were achieved in previously well-controlled patients without increasing the frequency of severe hypoglycemia. With initiation of real-time continuous glucose monitoring, the majority of subjects thought the DATA provided clear directions and thought the use of the DATA improved their glucose levels. The algorithm was frequently used at the onset of the study but, as the study progressed, subjects and parents reported using the DATA less often even though there was a trend for them to make more changes to their insulin regime as the study progressed. This may indicate they were learning from their glucose patterns and were individualizing their treatment plans.

There are several potential limitations to interpreting these results since the subjects as a group were not representative of all children with T1D: many had an excellent HbA1c, all had to have a home computer, and most were from highly motivated families. Since this study did not have a control group, there is no evidence that patients did better using the DATA algorithm than they would have without using the DATA. In a randomized trial of real-time continuous glucose monitoring in poorly controlled adolescents and adults with type 1 diabetes, a significant improvement in A1c levels was seen when subjects were not given specific guidelines (11). It is unknown if the subjects in the present study would have done equally well without using the DATA. Randomized clinical trials utilizing the DATA are needed to more fully evaluate the added value that the DATA provides in using real-time continuous sensors. It will also be important to use the DATA with other continuous glucose monitors which utilize different software. The results of this study provide evidence that these guidelines are acceptable to patients and can be used when real-time continuous glucose monitoring is initiated. The value of these guidelines in lowering HbA1c levels and reducing hypoglycemia will need to be determined in future randomized trials.

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References

1. Diabetes Research in Children Network (DirecNet) Study Group. Continuous Glucose Monitoring in Children with Type 1 Diabetes. The Journal of Pediatrics. 2007In press
2. Boukhors Y, Rabasa-Lhoret R, Langelier H, Soultan M, Lacroix A, Chiasson J. The use of information technology for the management of intensive insulin therapy in Type 1 Diabetes Mellitus. Diabetes Metab 2003;29:619–627. [PubMed: 14707892]

3. Miyako K, Kuromaru R, Kohno H, Hara T. Improved diabetes control by using 'Close Adjustment Algorithms'. Pediatr Int 2004;46:678–684. [PubMed: 15660867]
4. Skyler J, Skyler D, Seigler D, O'Sullivan M. Algorithms for adjustment of insulin dosage by patients who monitor blood glucose. Diabetes Care 1981;4:311–318. [PubMed: 7011749]
5. Davidson P, Steed R, Bode B. Glucommander: a computer-directed intravenous insulin system shown to be safe, simple, and effective in 120,618 hours of operation. Diabetes Care 2005;28:2418–2423. [PubMed: 16186273]
6. Furnary AP, Gao G, Grunkemeier GL, Wu Y, Zerr KJ, Bookin SO, Floten HS, Starr A. Continuous insulin infusion reduces mortality in patients with diabetes undergoing coronary artery bypass grafting. J Thorac Cardiovasc Surg 2003;125:1007–1021. [PubMed: 12771873]
7. Malmberg K, Ryden L, Efendic S, Herlitz J, Nicol P, Waldenstrom A, et al. Randomized trial of insulin-glucose infusion followed by subcutaneous insulin treatment in diabetic patients with acute myocardial infarction (DIGAMI study): effects on mortality at 1 year. J Am Coll Cardiol 1995;26:57–65. [PubMed: 7797776]
8. Trence D, Kelly J, Hirsch I. The rationale and management of hyperglycemia for in-patients with cardiovascular disease: time for change. J Clin Endocrinol Metab 2003;88:2430–2437. [PubMed: 12788838]
9. Van den Berghe G. How to compare adequacy of algorithms to control blood glucose in the intensive care unit? Crit Care 2004;8:151–152. [PubMed: 15153231]
10. Van den Berghe G, Wouters P, Weekers F, Verwaest C, Bruyninckx F, Schetz M, Vlasselaers D, Ferdinande P, Lauwers P, Bouillon R. Intensive Insulin Therapy in Critically Ill Patients. N Engl J Med 2001;345:1359–1367. [PubMed: 11794168]
11. Deiss D, Bolinder J, Riveline J-P, Battelino T, Bosi E, Tubiana-Rufi N, Kerr D, Phillip M. Improved glycemic control in poorly controlled patients with Type 1 Diabetes using Real-Time Continuous Glucose Monitoring. Diabetes Care 2006;29:2730–2732. [PubMed: 17130215]

Appendix: DirecNet Navigator Pilot Study Dose Adjustment Guidelines

Your Target Glucose Values Are

	< 7 years old	7–12 years old	> 12 years old
Pre Meal	90–180	80–150	70–130
Peak Post Meal	<200	<180	<180
Bedtime	110–200	100–180	90–150
Overnight	90–180	80–150	80–150

Pre-Meal Bolus Calculation

- At the start of the study, you will continue to use your current Insulin to carbohydrate ratios, correction factors and basal rates.
- To calculate correction doses, we will set your correction target at _____ mg/dL *(80–120)* during the day and _____ mg/dL *(80–150)* overnight. Smart pump patients will use 3–5 hour duration of action for the "insulin-on-board" calculator.

If your blood sugar is 70 mg/dL or lower: Begin to eat, but do not bolus until your blood sugar is above 80 mg/dL and then cover all of the carbohydrates in the meal.

If your blood sugar is above 70 mg/dL: Do your usual calculation of the amount of insulin needed to cover the carbohydrates in the meal and make a correction for high blood sugar. Look at the Navigator arrow and make the following adjustments:

- ↑ (90° Up) Increase meal dose by ____ % *(20%)*
- ↗ (45° Up) Increase meal dose by ____ % *(10%)*
- → (No change) No change in meal dose

- ↘ (45° Down) Decrease meal dose by ____ % *(10%)*
- ↓ (90° Down) Decrease meal dose by ____ % *(20%)*

ALERTS

High Alert

- We will set the high alert at _____mg/dL *(250–260)* and the projected high alert at medium.
- If the high or projected high alarm goes off during the day, check to make sure that you took your pre-meal or correction dose. If not, take the amount of insulin that you should have, as shown above.
- If you did take your meal bolus, then wait at least 2 hours before taking a correction dose, since there may be a lot of insulin left over from your last bolus.
- The correction dose should be calculated to correct to _____ mg/dL *(80–120)* during the day and _____ mg/dL *(80–150)* during the night.
- If you are using a “smart pump”, use the dose calculator to determine the amount of the correction dose (as per guidelines above).

Low Alert

- We will set the low alert at _____mg/dL *(60–70)*
- If the low alert goes off then treat with about 15 grams of carbohydrate.
- If the predicted low alert goes off, then treat with about 10 grams of carbohydrate.

You should check your blood sugar level with the Freestyle meter anytime a high or low alarm/event goes off in the first 2 weeks (high or low event is considered first alarm in a one-hour period). Your blood sugar will not need to be tested again for the next hour if the alarm continues. You should also check your blood sugar with the Freestyle meter if you have symptoms that are not consistent with Navigator values (for example: you feel low, but the Navigator does not show that you are low).

BASAL RATES

Adjusting overnight basal rates

You should review your Navigator blood sugar levels once or twice a week. If you find a blood sugar pattern not in the target range described above on at least 2 out of 3 nights, you should think about making a change to your overnight basal rates.

Before changing basal rates you should also make sure that there aren’t other reasons for high or low nighttime blood sugar levels, such as:

- Bedtime correction doses
- Missed meal or snack boluses
- Extremes in physical activity
- Meals with high fat or protein contents
- Illness
- Infusion site problem

Overnight blood sugar and basal rate patterns:

- Should be broken down into 2–4 hour time periods as set in the Navigator software: bedtime is 9 PM to midnight, nighttime is midnight to 4 AM, and prebreakfast (or dawn) is 4AM to 7 AM.
- Blood sugar patterns that suggest a change in the basal rate is needed are those where the blood sugar level is too high or too low or if the blood sugar level goes up or down by more than 20–30 mg/dL over the 3 to 4-hour time period.
- When there is a pattern for too high or too low blood sugar values in a given time period, then an adjustment should be made in the basal rate(s) beginning 1 hour **before** that time period. Example: There is a trend for your blood sugar levels to go up quickly between 4 and 7 AM. You should increase the basal rate beginning at 3 AM.
- Frequent small adjustments in the 0.025–0.1 U/hr are generally preferred over large changes.

Adjusting Daytime Bolus and Basal Rates

For adjustments of daytime doses: divide the day into time periods of about 3 hours. For example, on a typical school day: breakfast is 7AM to 10AM, pre lunch is 10AM to Noon, post lunch is noon to 3 PM, pre dinner is 3PM to 6PM, and Dinner is 6PM to 9 PM.

- Change the insulin to carbohydrate ratios if your blood sugar levels are too high or too low 2–3 hours after the meal.
- Change basal rates if the blood sugar values before the next meal are too high or low. For example, if an increase in the bolus dose before breakfast leads to good blood sugar levels after breakfast, but low blood sugar values before lunch, then lower the basal rate between breakfast and lunch.

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Table 1

Algorithm Satisfaction Questionnaire* (5 point Likert scale)

	Mean Score			No Opinion/Agree/Strongly Agree (3–5)			Agree or Strongly Agree (4–5)			Strongly Agree (5)		
	Wk 3	**Wk 7**	**Wk 13**	**Wk 3**	**Wk 7**	**Wk 13**	**Wk 3**	**Wk 7**	**Wk 13**	**Wk 3**	**Wk 7**	**Wk 13**
I felt that the Guidelines gave good, clear directions for how much insulin to give.												
Patients	3.9	3.8	3.6	100%	100%	100%	82%	68%	59%	9%	9%	5%
Parents	4.3	3.8	3.8	100%	93%	96%	96%	75%	73%	29%	11%	12%
The Guidelines often had me give a different dose of insulin than I would have without the Guidelines.**												
Patients	2.5	2.8	2.8	82%	86%	86%	59%	32%	32%	14%	5%	5%
Parents	3.1	2.9	2.7	57%	75%	77%	39%	36%	50%	7%	0%	0%
Using the Guidelines helped us to make good use of the Navigator readings.												
Patients	3.9	3.7	3.5	100%	95%	91%	86%	64%	50%	0%	9%	14%
Parents	4.0	3.7	3.6	100%	86%	88%	82%	68%	62%	18%	14%	12%

How did the Guidelines affect the blood sugar when used:	**Mean Score**			**Ok or Better (3–5)**			**Well or Very Well (4–5)**			**Very Well (5)**		
	Wk 3	Wk 7	Wk 13	Wk 3	Wk 7	Wk 13	Wk 3	Wk 7	Wk 13	Wk 3	Wk 7	Wk 13
for adjusting the pre-meal bolus?												
Patients	3.8	3.6	3.6	100%	100%	100%	68%	50%	55%	9%	9%	9%
Parents	3.8	3.5	3.6	96%	93%	96%	71%	50%	42%	14%	7%	19%
after an alarm from the Glucose sensor?												
Patients	4.0	3.7	3.5	100%	100%	100%	68%	55%	32%	27%	14%	14%
Parents	3.8	3.6	3.6	93%	89%	88%	64%	54%	54%	21%	14%	15%
for adjusting the basal insulin dose?												
Patients	3.7	3.5	3.2	100%	95%	82%	50%	41%	27%	18%	18%	18%
Parents	3.6	3.3	3.5	93%	89%	92%	50%	29%	35%	18%	11%	19%

* Patients: N=22 at 3, 7 and 13 weeks. Parents: N=28 at 3 and 7 weeks, N=26 at 13 weeks. Parents did not complete questionnaire if they were not involved in adjusting patient's insulin doses.

** Mean scores for negatively worded question (shaded) reverse scored so that a larger value always denotes a favorable response

Table 2

Frequency of use of the DATA*

How often have you used the Guidelines:	Mean Score			½ Time or More (3–5)			Most of the Time or Always (4–5)			Always (5)		
	Wk 3	Wk 7	Wk 13	Wk 3	Wk 7	Wk 13	Wk 3	Wk 7	Wk 13	Wk 3	Wk 7	Wk 13
for adjusting the pre-meal bolus?												
Patients	3.6	3.1	3.0	82%	64%	64%	68%	50%	41%	14%	5%	5%
Parents	3.3	3.1	3.2	64%	61%	69%	57%	50%	54%	21%	18%	15%
after an alarm from the Glucose sensor?												
Patients	3.8	3.4	3.1	86%	68%	59%	82%	59%	50%	23%	23%	18%
Parents	3.5	3.4	3.5	75%	61%	73%	64%	61%	62%	25%	36%	27%
for adjusting the basal insulin dose?												
Patients	3.0	2.7	2.6	59%	41%	41%	45%	41%	36%	23%	9%	14%
Parents	2.8	2.3	2.7	46%	32%	38%	39%	32%	35%	21%	7%	19%

* Patients: N=22 at 3, 7 and 13 weeks. Parents: N=28 at 3 and 7 weeks, N=26 at 13 weeks. Parents did not complete questionnaire if they were not involved in adjusting patient's insulin doses