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ORIGINAL ARTICLE

Insulin Bolusing Software: The Potential to Optimize Health Outcomes in Type 1 Diabetes Mellitus

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Abstract

Background:

Insulin bolusing calculators alleviate the burden of having to calculate insulin bolus doses for patients with type 1 diabetes mellitus (T1DM). Three important pieces of information are needed: a blood glucose monitoring (BGM) result, carbohydrates to be consumed, and the amount of insulin bolus delivered. The purpose of this study was to describe insulin pump adherence behaviors associated with the use of bolus calculators in youth who use Medtronic insulin pumps.

Methods:

Data were downloaded from the MiniMed Paradigm insulin pumps (Medtronic) of 31 youth with T1DM. Areas of adherence that were evaluated included fundamental insulin pump adherence behaviors (e.g., BGM, carbohydrate entry, and insulin bolusing), decisions about Wizard® recommendations, and three Wizard steps: BGM result–carbohydrate input–insulin bolus.

Results:

On average, patients conducted BGM ≥4 times/day on 69% of days, inputted carbohydrates ≥3 times/day on 63% of days, and insulin bolused ≥3 times/day on 85% of days. Participants generally followed Wizard recommendations. Finally, participants completed all three Wizard steps (BGM, carbohydrate input, insulin bolus) within 30 min for an average of 29% of boluses. Almost 3% of boluses that were preceded by Wizard use were delivered without conducting BGM or inputting carbohydrates.

Conclusion:

There was substantial variability in insulin pump adherence behaviors (e.g., days when no BGM occurred, reliance on basal insulin). Interventions targeting insulin pump adherence behaviors have the potential to optimize diabetes health outcomes and glycemic control. Improving insulin pump software reports is one promising avenue for improving adherence.

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Abbreviations: (A1C) hemoglobin A1c, (BG) blood glucose, (BGM) blood glucose monitoring, (T1DM) type 1 diabetes mellitus

Keywords: adherence, bolus calculator software, children and adolescents, insulin pumps, type 1 diabetes mellitus

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Introduction

Treatment adherence is the "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice."[1] Adherence assessment and intervention are instrumental in improving health outcomes, especially as the prevalence of chronic illnesses increases and treatments become more complex.[2] Adherence assessment in type 1 diabetes mellitus (T1DM) has unique advantages over other diseases because memory storage is a standard, objective feature of two essential components of the T1DM treatment regimen: blood glucose monitoring (BGM) and insulin pumps.

In 1963, Arnold Kadish designed the first insulin pump, but it was cumbersome and impractical. The Biostator, developed in 1974, was the first computerized insulin pump, but it was similarly problematic. Later insulin pumps continued to present problems, including inadequate performance, lack of reliability, and excessive weight.[3] However, in the 1990s, many of these practical issues were resolved and pager-sized insulin pumps were introduced. The technology of insulin pumps is even more sophisticated than ever, allowing for data storage of vast amounts of insulin pump adherence behaviors, including frequency of infusion set site changes, basal rates, BGM results and how they relate to the administration of insulin boluses, and bolus calculator data. These data can be downloaded into compatible software programs to aid a diabetes health care provider in objective measurement of T1DM adherence and, equally important, in clinical decision making. Moreover, these same data are available for personal download to aid in patient decision making about their diabetes management. Current estimates suggest that 20–25% of people with T1DM use the insulin pump in the United States.[3]

Overview of Insulin Pump Bolus Calculators

Bolus calculators contained in the insulin pump require two essential pieces of information: BGM results and carbohydrates to be consumed (if eating). Bolus calculators alleviate patient burden of having to calculate insulin bolus doses, and they minimize the likelihood of calculation errors. Presumably, use of the bolus calculator will result in more accurate insulin doses and predictability for insulin pump users.[4] Some studies have even demonstrated that using the bolus calculator feature results in better glycemic control.[5] Bolus calculators are quite sophisticated in that the underlying algorithm takes into account the amount of basal insulin being delivered and "insulin on board" (i.e., the amount of insulin remaining in the body from previous insulin boluses), current BG level, target BG level, amount of carbohydrates consumed, insulin-to-carbohydrate ratio, and an approximation of the insulin action curve.[4] Zisser and colleagues[6] noted, however, that differences exist in each pump manufacturer's underlying algorithm.

Several insulin pumps contain bolus calculators: MiniMed Paradigm® Real-Time Revel™ (Medtronic, Northridge, CA), OmniPod® (Insulet Corp., Bedford, MA), and OneTouch® Ping® (Animas Corp., West Chester, PA). The MiniMed Paradigm Real-Time Revel insulin pump is compatible with the OneTouch UltraLink® and the Bayer CONTOUR® Link (Bayer Health Care LLC, Terrytown, NY) BG meters, whereas the OneTouch Ping insulin pump has a compatible meter with the same name. These meters wirelessly transmit BGM results to the insulin pump, thereby alleviating the patient of the added task of manually entering results. The OmniPod insulin pump has the FreeStyle® (Abbott Laboratories, Abbott Park, IL) BG meter built into it and contains the Personal Diabetes Manager®, which wirelessly manages insulin. The ACCU-CHEK® Spirit (Roche Diagnostics Corp, Indianapolis, IN), OmniPod, and OneTouch Ping insulin pumps contain a particularly impressive advancement in bolus calculator software: databases of common foods.

Most bolus calculator studies have focused on demonstrating efficacy.[6,7] Although bolus software technology has the potential to lead to improved glycemic control, the performance of the software is only as good as its user. It is essential that the user be properly educated in using the bolus calculator to maximize the likelihood of positive health outcomes.[8] Ensuring proper use is especially important in children/adolescents; however, to our knowledge, studies of bolus calculators have included only adults.[6,9,10] Therefore, the purpose of this study was to describe insulin pump adherence behaviors associated with the use of insulin pump bolusing calculators in youth[11] using a Medtronic insulin pump.

The Medtronic Bolus Wizard Calculator

Optimal use of the Medtronic Bolus Wizard® Calculator (hereafter called the Wizard) requires the following steps: (1) obtain BG result, (2) calculate and enter the number of carbohydrates to be consumed (carbohydrate entry is 0 if food is not being consumed and only a correction bolus to lower high BG is desired), and (3) calculate the recommended insulin dose by the Wizard, which is either accepted or adjusted by the patient. However, various combinations of these steps can occur as described in **Table 1**.

Table 1.
Possible Combinations of Wizard Behaviors

BGM Result	Carbohydrate Entry	Bolus Delivery
X	X	X
X	–	X
–	X	X
–	–	X
X	X	–
X	–	–

Methods

Participants in this study were part of a larger longitudinal observational study aimed at assessing BGM and insulin pump adherence patterns. Data for the current study were obtained from 31 youth (ages 7–19 years; three participants ≥18 years) with T1DM for ≥1 year who were using MiniMed insulin pumps (Medtronic). Sample characteristics are found in **Table 2**. All participants used the OneTouch Ultralink (LifeScan, Inc., Milpitas, CA) BG meter, which has a memory capacity of 500 BG readings and wirelessly communicates with the Medtronic insulin pump. LifeScan, Inc. provided BG strips for the first 18 patients. Independent *t*-tests revealed no significant differences between these patients and the remaining study participants on key variables such as child age, diabetes duration, hemoglobin A1c (A1C), daily average number of BG results, carbohydrate inputs, and insulin boluses delivered (statistics not reported).

Table 2.
Sample Characteristics

Variable	*N* (%) or mean ± standard deviation; range
Age (years)	13.11 ± 3.41; 7–19
Sex	
Female	54.8%
Male	45.2%
Race	
Caucasian	87.5%
Non-Caucasian	13.5%
Diabetes duration (years)	6.16 ± 3.21; 1.37–12.40
A1C	8.34% ± 1.14%; 6.2–11.9
Insulin pump use duration (years)	3.99 ± 2.41; 0.57–8.63
Insulin pump model	
515	1 (3.23%)
522	8 (25.81%)
523	3 (9.68%)
715	5 (16.13%)
722	10 (32.26%)
723	4 (12.90%)

All available data were downloaded from each patient's insulin pump during the diabetes clinic visit. The amount of data that each insulin pump held varied from 10 to 319 days of data (mean = 102.52 + 63.29 days; median = 91 days). Because this was an observational study of insulin pump use, all available data were used in the analyses. The patient's A1C representing the average BG level during the past 2.5 to 3 months[12] was obtained using a Siemens Healthcare Diagnostics DCA Vantage (reference range 4.2–6.5%), which is certified as having documented traceability to the Diabetes Control and Complications Trial reference method by the National Glycohemoglobin Standardization Program. Informed written consent and assent were obtained from all participants before enrollment in the study. The Florida State University Institutional Review Board approved this study.

Evaluation of Insulin Pump Adherence

The insulin pump permits the objective assessment of adherence behaviors of the user, something that is impossible for patients who deliver insulin using daily injections. These behaviors fall into three categories: (1) fundamental insulin pump adherence behaviors, (2) decisions about Wizard recommendations, and (3) BGM/carbohydrate counting/insulin bolusing behaviors.

Fundamental Insulin Pump Adherence Behaviors

To achieve optimal use of insulin pumps, patients must engage in BGM, carbohydrate counting, and insulin bolusing.

Although the Wizard calculates the amount of insulin to be delivered, the patient must make a decision about what to do (i.e., deliver insulin or not). In accordance with the American Diabetes Association's clinical practice recommendations,[13] we defined insulin pump adherence as comprising the following fundamental behaviors: (1) BGM ≥4 times/day, (2) carbohydrate counting and entry ≥3 times/day, and (3) insulin bolusing ≥3 times/day.

Because it is unreasonable to expect 100% adherence daily, we surveyed T1DM health care providers (e.g., certified diabetes educators, endocrinologists; n = 7) who provided consensus about the following adherence behaviors targets: BGM ≥4 times/day ≥90% of days; carbohydrate input ≥3 times/day ≥90% of days; and insulin bolusing ≥3 times/day ≥90% of days.

Decisions about the Wizard Recommendations

We evaluated how well participants followed Wizard recommendations by determining percentages of boluses that (1) were delivered in accordance with Wizard recommendations, (2) exceeded Wizard recommendations, and (3) were less than Wizard recommendations. Although no guidelines exist for when a patient should override the Wizard's calculation, we used a cut-off criterion such that Wizard recommendations should be followed for ≥90% of boluses.

Blood Glucose Monitoring, Carbohydrate Counting, Insulin Bolusing Behaviors

Relations between BGM, carbohydrate counting, and insulin bolusing are outlined in **Table 1**. The occurrence of these behaviors was restricted to a 30 min window.

Changes to Wizard Settings

The percentage of participants that made at least one change to basal rates, bolus ratios, and insulin sensitivity settings during the study period were determined. Unfortunately, we were not able to distinguish between the motivation for change in the current data (i.e., physician recommendation versus patient's independent decision).

Results

Insulin Pump Adherence Behaviors

Fundamental Insulin Pump Adherence Behaviors

Patients conducted BGM ≥4 times/day an average of 69.40% ± 34.18% of days, with notable variability (see **Table 3**). Fifteen patients failed to conduct any BGM on at least one day. One patient never conducted BGM ≥4 times/day; the maximum number of BGM results on any given day was 3. In contrast, all other patients' maximum number of BGM results on any day was ≥5 and 54.8% had a maximum number of daily BGM results ≥10. A total of 48.39% of patients conducted BGM ≥4 times/day for ≥90% of days.

Table 3.
Fundamental Insulin Pump Behaviors

	Mean ± standard deviation; range
BGM ≥4 times/day	69.40% ± 34.18%; 0–100
Carbohydrate input ≥3 times/day	62.55% ± 33.56%; 1.31–98.21
Insulin bolus ≥3 times/day	84.57% ± 22.05%; 12.96–100

Patients inputted carbohydrates ≥3 times/day an average of 62.55% ± 33.56% of days. Substantial variability occurred regarding carbohydrate inputs as well. For example, 20 patients (64.52%) failed to input carbohydrates on at least one day. One patient entered carbohydrates only 1.13% of days, whereas several patients who failed to input carbohydrates on some days inputted carbohydrates as many as 10 times on other days. Only 29.03% of patients inputted carbohydrates ≥3 times/day ≥90% of days.

Finally, patients administered an insulin bolus ≥3 times/day an average of 84.57% ± 22.05% of days. Nine patients relied on only basal insulin at least one day (i.e., they did not administer an insulin bolus), but these same patients' maximum bolus delivery ranged from 5–13 boluses/day. A total of 64.5% of patients delivered ≥3 boluses/day ≥90% of days, with seven (22.58%) administering ≥3 boluses/day 100% of days.

Relations between Fundamental Insulin Pump Adherence Behaviors and Hemoglobin A1c

Overall, better glycemic control was associated with an increase in the frequency of fundamental insulin pump adherence behaviors. As the percentage of days that BGM occurred ≥4 times/day increased, A1C decreased (r = -0.53;

$p < .01$). Similarly, as the percentage of days that carbohydrate input occurred ≥3 times/day increased, A1C decreased (r = -0.34; $p < .058$). Finally, as the percentage of days that insulin bolusing occurred ≥3 times/day, A1C decreased (r = -0.37; $p < .05$).

Relations between Fundamental Insulin Pump Adherence Behaviors and Age

Overall, younger age was associated with an increase in the frequency of fundamental insulin pump adherence behaviors. As the percentage of days that BGM occurred ≥4 times/day increased, age decreased (r = -0.54; $p < .01$). Similarly, as the percentage of days that carbohydrate input occurred ≥3 times/day increased, age decreased (r = -0.46; $p < .05$). Finally, as the percentage of days that insulin bolusing occurred ≥3 times/day increased, age decreased (r = -0.46; $p < .01$).

Decisions about the Wizard Recommendations

The average patient delivered the bolus amount recommended by the Wizard for 76.82% ± 22.89% of boluses. Although most patients followed the recommendations of the Wizard for most of their bolus deliveries, variability was observed. One patient followed the Wizard recommendation for only 7.67% of boluses. Thirteen patients (41.94%) followed the Wizard recommendation ≥90% of boluses. In contrast, 12.23% of boluses ± 15.85% exceeded the amount recommended by the Wizard. Seven patients (22.6%) gave more insulin than the Wizard recommended for 30% of boluses. Ten patients (32.2%) always followed the Wizard recommendation exactly. Finally, for 11.0% ± 14.54% of boluses, patients administered less insulin than the Wizard recommended. Two patients never gave less insulin than recommended, whereas one patient gave less insulin than recommended for 82.65% of boluses.

Wizard Steps: Blood Glucose Monitoring Result, Carbohydrate Input, Insulin Bolus

Descriptive statistics for all combinations of the three Wizard steps (i.e., BGM result, carbohydrate input, insulin bolus delivery) occurring within 30 min are found in **Table 4**. Overall, the three steps were completed within 30 min for 29% of boluses. One patient completed all three steps within 30 min for only 1% of boluses, whereas, another patient completed all three steps within 30 min for 73% of boluses.

Table 4.
Blood Glucose Monitoring, Carbohydrate Counting, and Insulin Bolusing Behaviors

	Mean ± standard deviation; range
BGM, carbohydrate entry, bolus delivery	28.9% ± 20.46%; 1.14–72.92
BGM, no carbohydrate entry, bolus delivery	18.11% ± 12.25%; 1.73–48.52
No BGM, carbohydrate entry, bolus delivery	31.03% ± 19.29%; 0.65–91.81
No BGM, no carbohydrate entry, bolus delivery	2.54% ± 6.56%; 0–27.39
BGM, carbohydrate entry, no bolus delivery	0.31% ± 1.5%; 0–8.45
BGM, no carbohydrate entry, no bolus delivery	0.89% ± 3.47%; 0–18.78

There was also great variability regarding bolus delivery in the absence of BGM and carbohydrate inputs. Some patients almost always included BGM while also inputting carbohydrates and delivering a bolus within 30 min. However, other patients routinely omitted the BGM result but inputted carbohydrates and delivered a bolus. In fact, one patient did this for 92% boluses that were preceded by Wizard use. Bolusing in the absence of BGM and carbohydrate input is arguably the least desirable insulin pump adherence behavior; it occurred, on average, for 2.5% of the boluses delivered. A total of 27% of one patient's boluses were delivered in the absence of a BGM result or carbohydrate input. In contrast, 12 patients (38.7%) never delivered boluses without a BGM result or carbohydrate input.

Changes to Wizard Settings

The percentage of patients who made at least one change to their Wizard settings are as follows: basal rates (22.58%), carbohydrate ratio (58.06%), and insulin sensitivity (19.35%).

Discussion

To our knowledge, this is the first study to evaluate insulin pump adherence behaviors related to bolus calculator software in youth with T1DM. Results revealed that participants demonstrated higher adherence to administering insulin boluses ≥3 times/day (85% of days). Participants were less adherent to conducting BGM ≥4 times/day (69% of days) and to inputting carbohydrates into their pumps (63% of days). Better adherence was associated with younger age. Almost 3% of the boluses that were preceded by Wizard use were delivered without conducting BGM or entering carbohydrates. Study results also demonstrated that participants followed Wizard recommendations the vast majority of the time. Finally, participants completed all three Wizard steps within 30 min, on average, for 29% of boluses.

Although perfect adherence across all diabetes tasks is impossible, the optimal level of adherence needed for good health outcomes remains unknown. However, it seems reasonable that variability in T1DM adherence impacts glycemic excursions and overall glycemic control. Our study highlights the extreme intrapatient and interpatient variability across every insulin pump adherence behavior. For example, there were days when some participants did not conduct any BGM, input carbohydrates, or deliver an insulin bolus. Lack of adherence to insulin bolusing is particularly alarming. While relying on basal insulin is better than no insulin at all, optimal glycemic control is not likely to be attained when boluses are not administered. Consistent with other studies, our findings demonstrated that greater BGM and insulin bolus delivery frequency was associated with better glycemic control.[14–16] Taken together, our results highlight the need to provide intervention to youth focused on insulin pump use, and bolus calculator software specifically, especially in older adolescents who demonstrate poorer adherence than younger children. Perhaps reducing variability in an individual patient's adherence would lead to better glycemic control. In addition, it would be helpful to understand the patient's decision-making process in overriding the recommendations of the Wizard.

For children and adolescents, one way to improve their understanding of their adherence is through the individual reports generated by insulin pump software. The Medtronic Carelink® software provides both patients and their diabetes health care providers with an array of information about their insulin pump use, including numerical and graphical representation of the BGM and carbohydrate input frequency and insulin boluses delivered *by day*. Summary statistics are provided regarding average BGM, BGM readings above and below target, average daily carbohydrates, and average daily basal insulin and bolus amounts. However, we believe that the quality of reports could be more user-friendly. We propose that providing an analysis of specific insulin pump adherence behaviors would lead to improvements in the T1DM clinical care and in overall health outcomes such as glycemic control. In its current format, pages of Carelink reports have to be visually scanned and general patterns derived for specific adherence behaviors. One potential improvement could be to provide aggregate statistics of the behaviors that we presented in our results accompanied by a breakdown and focus on the variability that is occurring for each patient. This information could facilitate focused discussions between the patient and health care provider (e.g., Why does no BGM occur one day, but then 12 results occur on a different day?). A problem-solving intervention to conduct BGM more consistently across days could be implemented. In fact, we are currently conducting a National Institutes of Health-funded study in which we download insulin pumps in a diabetes clinic and immediately generate a more user-friendly insulin pump adherence behaviors report, which is reviewed with the child or adolescent and his/her parent. In addition, we have refined analyses to evaluate decision making with the Wizard in the context of low, in target range, high, and very high BGM results.

Modern insulin pump technology has the potential to optimize diabetes health outcomes, but it is not without faults. A limitation of the current study is that we were not able to use data files in which the BG meter and insulin pump times and dates were not synchronized because downloading and data analytic problems occurred; therefore, automatic synchronization would be ideal. In the absence of automatic synchronization, researchers need to incorporate ensuring synchronization into their protocols. We found that, even within the *same* BG meter file, times can be off by 60 min for some days and 5 min on other days. We also found some downloaded files contained dates from several years ago. Because insulin pump data storage capacity is limited, it is unlikely that the old data is accurate. Moreover, some insulin pumps can store many months' worth (e.g., 10 months) of data, whereas other pumps contain very limited amounts of data (e.g., 2 months). Data storage capacity that exceeds the standard diabetes clinic appointment interval would be ideal (e.g., 4–5 months). Finally, we discovered a date that contained 48 h, not 24 h. The BGM and insulin data did not simply repeat itself at the beginning of the 25th hour and the dates before and after were chronologically ordered.

Conclusions

Although the sample size of this study was small, the results highlight the importance of attending to specific insulin pump adherence behaviors in youth with T1DM. Future research should aim to improve the quality of clinical data in reports that are provided to patients and their diabetes health care team. In addition, studies focused on providing tailored and focused intervention using these reports have the potential to improve both immediate and long-term health outcomes in youth with T1DM.

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