DIABETES TECHNOLOGY & THERAPEUTICS
Volume 14, Number 10, 2012

DOI: 10.1089/dia.2012.0122

DTT
Diabetes Technology & Therapeutics

ORIGINAL ARTICLE

Patient Perspectives on Personalized Glucose Advisory Systems for Type 1 Diabetes Management

Jaclyn A. Shepard, Psy.D.,[1] Linda Gonder-Frederick, Ph.D.,[1]
Karen Vajda, B.A.,[1] and Boris Kovatchev, Ph.D.[2]

Abstract

Background: Diabetes technology is rapidly advancing toward fully automated glucose control systems, but little is known about patient perspectives on these systems. This study aimed to gather qualitative and quantitative data on patient attitudes and concerns about using a personalized glucose advisory system (PGASystem) for diabetes management.
Subjects and Methods: Fifty-six adults with type 1 diabetes on insulin pump therapy participated in focus group interviews following use of an insulin pump and continuous glucose monitoring for 4 weeks in a parent study to develop a PGASystem. Focus groups were transcribed and coded for thematic content.
Results: All participants endorsed the desire to use a PGASystem, and the majority wanted advice from the system on all aspects of insulin delivery. However, participants indicated that they might be reluctant to follow such advice because of the following concerns: how the advice was generated, relinquishing control to automated technology, and inadequate personalization of the system. Participants believed the system would need to consider numerous factors related to their food, activities, and other personal information to provide optimally individualized advice. The majority also reported difficulties with behavioral event recording on their insulin pumps, and approximately one-third endorsed difficulty with accurate carbohydrate counting.
Conclusions: Adults with type 1 diabetes appear to be enthusiastic about using a PGASystem system for their diabetes management but also have significant concerns affecting their overall willingness to follow such a system's advice. Addressing these concerns will be crucial in the future development of glucose advisory and control technology.

Introduction

Advancements in diabetes management technology are now aimed at developing fully automated glucose control systems, also known as the "artificial pancreas." With these systems still in their infancy, research has focused almost exclusively on device development and performance.[1–5] Only two previous studies have explored patient perspectives and reactions to this emerging technology.[6,7] However, in both of these surveys, participants (or pediatric patients' parents) had no or very limited experience using the key components of any glucose control system—insulin pumps and continuous glucose monitoring (CGM) devices. It is critical to examine patient-centered factors, such as perceived barriers, concerns, and desired features and functions, which will undoubtedly play a large role in future patient adoption and use of advanced diabetes management technologies.

The purpose of this study was to conduct a preliminary investigation into patient attitudes and concerns related to personalized glucose advisory systems (PGASystems) in a group of patients with experience in using both insulin pump and CGM technology. Because insulin pumps and CGM devices often contain event (e.g., meals, physical activity) recording technology to assist patients in interpreting glucose patterns, the study also assessed patients' perceived confidence in their ability to perform this task. A portion of this study was presented in abstract at the 71st Annual Scientific Sessions of the American Diabetes Association, San Diego, California, June 24–28, 2011.[8]

Subjects and Methods

Participants

In total, 56 adults with type 1 diabetes participated in the focus groups. Mean participant age was 41 ± 12.2 years, 59% were female, the majority were white (95%), and 50% were employed in professional occupations. Mean glycosylated hemoglobin (HbA1c) was 7.7 ± 1.2%, with a mean duration of diabetes of 24.1 ± 11.0 years and insulin pump usage of 10 ± 5.8 years. Participants were recruited for the parent study, described below, through Institutional Review Board–approved flyers, routine diabetes clinic visits, physician referrals, and lists of prior participants who had agreed to be contacted for future studies. Eligibility criteria included 21 to 65 years of age,

[1]Behavioral Medicine Center and [2]Center for Diabetes Technology, University of Virginia, Charlottesville, Virginia.

duration of type 1 diabetes of at least 2 years, use of an insulin pump for at least 6 months, active use of a bolus calculator function with the current insulin pump, and demonstration of appropriate mental status for study completion. Participants were compensated $250 for completing the parent study. Both studies were approved by the local Institutional Review Board.

Focus group protocol and data collection

Focus groups were conducted after participants completed a 4-week protocol from a parent study, which was designed to collect glucose, insulin, and behavioral (e.g., carbohydrate count) data to be used for the subsequent development of a PGASystem. Participants used an Omnipod® (Insulet Corp., Bedford, MA) insulin pump and DexCom (San Diego, CA) SEVEN® Plus CGM device for 4 consecutive weeks, during which time glucose readings, insulin delivery, and carbohydrate count data were recorded. Self-monitoring of blood glucose with the FreeStyle® (Abbott Diabetes Care, Abbott Park, IL) glucose meter integrated into the Omnipod insulin pump controller was required at least four times per day. At the time of self-monitoring of blood glucose readings, and more often if they desired, participants also recorded (or "tagged") mealtime behaviors (e.g., not eating, dining out, meal fat content) as well as level of physical activity (minimal, moderate, strenuous) in their insulin pumps.

Focus group methodology was chosen to obtain qualitative and quantitative data on participants' desire to use glucose advisory systems to manage their diabetes, their concerns about and desired features and functions of these systems, and their perceived confidence with behavioral event recording. The semistructured interview was developed by the first two authors, who also facilitated the focus groups. At the outset of each interview, the PGASystem was described to participants as a system composed of a CGM device and insulin pump, into which they would input daily information about their insulin, food, and physical activity (similar to the behavioral tagging procedures they followed in the parent study). The system would then use their data to create personalized algorithms and advice about various aspects of their diabetes management, such as suggestions regarding bolus and basal rate dosing. The interview consisted of open-ended (e.g., "What types of advice would you want a glucose advisory system to give you?"), multiple choice (e.g., "On average, how often did you record/tag behavioral events each day?"), and dichotomous (e.g., "Would you want to use a glucose advisory system that required you to use a CGM device and insulin pump, to help you control your glucose?") questions. Two to seven participants attended each focus group, which lasted approximately 2 hours. Eight participants could not attend a group session because of geographic location or scheduling difficulties, so individual telephone interviews were conducted. All interviews were transcribed verbatim by two team members (J.A.S. and K.V.) and analyzed for thematic content using the qualitative data analysis approach of Themeing the Data.[9]

Results

Desire to use a PGASystem

All 56 participants reported that they would want to use a PGASystem for diabetes management. Regarding types of potential advice, all participants reported interest in receiving suggestions on correction boluses. The majority of participants also reported interest in suggested changes in basal rates (92.9%) and meal boluses or insulin-to-carbohydrate ratios (94.6%), as well as warnings about hypoglycemia risk (85.7%). However, despite this level of interest, participants acknowledged they might not always be willing to follow the advice given by a PGASystem. For example, fewer than half of participants (44.2%) stated they would be likely to follow suggestions regarding basal rate changes. Reasons given for this reluctance were concerns about how the system generated the advice and risks associated with changing basal rates too frequently or based on too little information. The majority of participants did not want to receive advice on basal rate changes on a daily basis, but rather every 3 days at most.

Slightly more of the participants reported a willingness to follow suggestions on correction boluses (53.6%) and meal boluses (60.4%). Participants again expressed the desire to know what type of information the system used to generate advice. They also indicated that, in order to follow suggestions about insulin boluses, they would need assurance that the system took into consideration specific types of information about their projected physical activity, fat content of meals, and previous blood glucose trends. The majority of participants (96.4%) wanted to receive meal bolus advice on demand and correction bolus advice at a set blood glucose threshold, rather than at specific time intervals. For hypoglycemia warnings provided by the PGASystem, nearly all participants (91.7%) believed they would be willing to heed these warnings, although only approximately half (53.6%) wanted this information to be displayed continuously.

Concerns about use of a PGASystem

Three prominent themes emerged related to participants' attitudes toward using a PGASystem for their diabetes management. A primary concern, as noted above, was the need to understand how the advice was generated. Specifically, many participants reported concerns about how many days of insulin and glucose data the system would take into consideration to generate suggestions, with some stating that they would want to see the mathematical formulas or algorithms. Many participants also expressed concern about the accuracy and personalization of advice received. The majority (87.5%) of participants reported that they looked at CGM readings more than 10 times daily on average but also expressed concerns about the overall accuracy of the readings and the impact this could have on PGASystems.

Difficulty trusting the technology and relinquishing personal control of daily diabetes management to an automated system was another identified theme. Nearly all participants emphasized the importance of being able to override the system's advice, if desired. Lastly, participants underscored the importance of how much personalized information they believed the system would need concerning their individual glucose patterns, behaviors, and planned activities in order to generate accurate advice. They outlined several factors that they believed significantly affect their glucose levels and insulin requirements and that the system would need to consider in order to provide optimal personalized glucose control. Examples of these factors, which are presented in Table 1, include stress levels, travel, alcohol consumption, and shift work.

Table 1. Participant Suggestions for Information a Personalized Glucose Advisory System Would Need to Consider for Optimal Personalization

Types of information
• Duration of physical activities (in addition to intensity)
• Food protein and fat content
• Hormonal changes in women (i.e., menstrual cycle, menopause)
• Pregnancy and nursing
• Psychological/physical stress
• Changes in schedules/routines
• Shift work/night work/on call work
• Weekend/weekday
• Travel/time zones
• Other medications
• Pramlintide acetate use
• Alcohol consumption
• Planned activities for the near future
• Surgery/medical procedures

Behavioral event recording

Approximately one-third of participants (32.1%) completed eight behavioral tags per day as instructed for the parent study, and more than half (58.9%) completed nine or more per day. Despite this high adherence rate, many participants reported having difficulty accurately recording behaviors. The majority endorsed difficulty with meal fat content, with 69% and 54% reporting problems determining low and high fat content, respectively. A similar number of participants (32.1%) reported difficulty with carbohydrate counting. For physical activity intensity, more participants had difficulty tagging moderate activity (47.4%), whereas minimal and strenuous activity levels were less problematic (29.0% and 26.7%, respectively).

Discussion

This is the first study to date to examine patient perspectives on use of PGASystems in patients who have engaged in extended use of the two necessary components of such a system—insulin pumps and CGM devices. These findings clearly indicate that many adults who already use technology (i.e., insulin pump) to manage their diabetes are interested in using a glucose advisory system that would provide feedback about their diabetes management. However, it also appears that these patients have significant concerns that could pose barriers to future adoption and utilization of this technology.

Similar to these findings, the two previous studies[6,7] on patient and parent perspectives on the use of closed-loop glucose control reported encouraging results regarding enthusiasm toward such devices. In a study of parental attitudes toward overnight closed-loop control for their type 1 children,[6] a majority of parents indicated via anonymous survey that they would trust the automated system to accurately calculate and deliver insulin. Nearly all parents denied worrying about their children using a closed-loop system for overnight insulin delivery, although some noted that having results from clinical trials would promote increased trust in the system. Although parental enthusiasm for use of automated systems for their children's diabetes management is consistent with our findings in adults, these two groups expressed different levels of trust in these systems. Specifically, adults in our study expressed significant concern about whether or not a PGASystem would be accurate, while parents in the previous study reported virtually no concerns about overnight closed-loop control. Factors contributing to these differences may include the small number of parents ($n = 19$) who participated in the anonymous survey, as well as the fact that none of the parents had prior experience with CGM.

In another study investigating future patient acceptance of closed-loop systems,[7] 132 adults on insulin pump therapy were surveyed using a questionnaire based on the technology acceptance model.[10] Similar to the above findings, patient enthusiasm for use of these systems was high, and the majority of participants rated the artificial pancreas high on perceived usefulness, ease of use, and trust (i.e., accuracy of measuring blood glucose levels and insulin dosing). However, the majority of these patients had no, or very limited, experience with CGM, and they were only provided with a detailed written description of a closed-loop system and its components. Therefore, although these studies indicate a high level of enthusiasm for use of control systems, our findings suggest that more hands-on experience with the technology used in these systems can influence patient trust and willingness to follow automated advice in vivo.

In this exploratory study, we identified several attitudinal barriers to patient adoption and utilization of PGASystems, including patient concerns about how the system's advice will be generated, inadequate personalization of systems regarding individual glucose patterns, behaviors, and planned activities, and relinquishing personal control of daily diabetes management to automated technology. Our findings indicate that perceived control and self-efficacy play an important role in diabetes management, perhaps especially for patients who are highly engaged in intensive self-treatment regimens such as insulin pump therapy. Somewhat ironically, this patient population, which may be reluctant to relinquish personal control over diabetes management, is most likely the group who will also be early adopters of glucose advisory systems. Therefore, given our sophisticated, highly motivated sample, results from this study may not represent perspectives of the type 1 diabetes population as a whole. Future, larger-scale studies should include patients who are more representative of the general type 1 diabetes population in order to ascertain level of interest, attitudes, and concerns in those who are perhaps more reluctant to incorporate sophisticated technology into their diabetes management. Likewise, more research is needed to predict patient reactions to these systems and to identify what is needed to help prepare patients for the transition to newly emerging technologies. Although beyond the scope of our current study, an important consideration in patient adoption of glucose advisory systems is the user–interface design, or how the individual interacts with the system. Understanding patient goals, expectations, and barriers in the use of these systems, as well as providing adequate and relevant patient education and training, will be crucial components in promoting widespread adoption and optimal utilization of advancing technologies.

Acknowledgments

This study was supported by grants DK 085623 and DP3 DK 094331 from the National Institutes of Health. The authors would like to recognize Colleen Karvetski, Ph.D., Molly McElwee, R.N., and Mary Oliveri, CCRP, for their assistance

with organizing and transcribing a portion of the focus group interviews.

Author Disclosure Statement

L.G.-F. has received research funding, study material support, or consulting fees from Abbott Laboratories, AstraZeneca, Animas Corporation, Dexcom, Inc., and Merck & Co., Inc. B.K. has received study material support from Dexcom, Inc. and Insulet Corporation and currently serves on the Advisory Board for Animas Corporation. No competing financial interests exist for J.S. and K.V.

References

1. Cobelli C, Renard E, Kovatchev B: Artificial pancreas: past, present, and future. Diabetes 2011;60:2672–2682.
2. Dassau E, Atlas E, Phillip M: Closing the loop. Int J Clin Pract Suppl 2011;65:20–25.
3. Zisser H: Clinical hurdles and possible solutions in the implementation of closed-loop control in type 1 diabetes mellitus. J Diabetes Sci Technol 2011;5:1283–1286.
4. Hovorka R. The future of continuous glucose monitoring: closed loop. Curr Diabetes Rev 2008;4:269–279.
5. Penfornis A, Personeni E, Borot S: Evolution of devices in diabetes management. Diabetes Technol Ther 2011;13 (Suppl 1):S93–S102.
6. Elleri D, Acerini CL, Allen JM, Hayes J, Pesterfield C, Wilinska ME, Dunger DB, Hovorka R: Parental attitudes towards overnight closed loop glucose control in children with type 1 diabetes. Diabetes Technol Ther 2010;12:35–39.
7. van Bon AC, Brouwer TB, von Basum G, Hoekstra JB, DeVries JH: Future acceptance of an artificial pancreas. Diabetes Technol Ther 2011;13:731–736.
8. Gonder-Frederick L, Shepard J, Vajda K, McElwee M, Oliveri M, Hughes C, Patek S, Kovatchev B: Patient perspectives toward advisory control (AC) and closed-loop control (CLC) systems [abstract]. Diabetes 2011;60(Suppl 1): 849-P.
9. Saldana J: The Coding Manual for Qualitative Researchers. London: SAGE Publications Ltd., 2009.
10. Davis FD: Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989;13: 319–340.

Address correspondence to:
Linda Gonder-Frederick, Ph.D.
Box 800223
Behavioral Medicine Center
University of Virginia
Charlottesville, VA 22908

E-mail: lag3g@virginia.edu