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Psychosocial Aspects of Diabetes Technologies: Commentary on the Current Status of the Evidence and Suggestions for Future Directions

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Abstract

Diabetes technologies, including continuous glucose monitors, insulin pumps, and automated insulin delivery systems offer the possibility of improving glycemic outcomes, including reduced hemoglobin A1c, increased time in range, and reduced hypoglycemia. Given the rapid expansion in the use of diabetes technology over the past few years, and touted promise of these devices for improving both clinical and psychosocial outcomes, it is critically important to understand issues in technology adoption, equity in access, maintaining long-term usage, opportunities for expanded device benefit, and limitations of the existing evidence base. We provide a brief overview of the status of the literature—with a focus on psychosocial outcomes—and provide recommendations for future work and considerations in clinical applications. Despite the wealth of the existing literature exploring psychosocial outcomes, there is substantial room to expand our current knowledge base to more comprehensively address reasons for differential effects, with increased attention to issues of health equity and data harmonization around patient-reported outcomes.

Keywords

automated insulin delivery, continuous glucose monitors, psychosocial aspects, type 1 diabetes

Background

Diabetes technologies, including continuous glucose monitors (CGMs), insulin pumps, and automated insulin delivery (AID) systems, offer the possibility of improving glycemic outcomes, including reduced A1c, increased time in range, and reduced hypoglycemia.[1-3] Technology use has increased worldwide, with rates of CGM use in both youth and adults rising. In a US study assessing national trends in CGM use among individuals with commercial insurance, the rate of CGM use rose from 20% between 2010 and 2013 to 49.78% in 2016 to 2019, a 2.5-fold increase in less than ten years' time.[4] In the United Kingdom, the rate of CGM use has increased to eight in ten adults with type 1 diabetes (T1D) in the span of a few years.[5-7] Insulin pump use has seen an increase in uptake as well, with 63% of individuals using pumps in 2019 in the United States, up from 57% in 2012.[5] Prevalence among minoritized groups, however, remains significantly lower with non-Hispanic white individuals almost twice as likely as black and Hispanic individuals to access such technologies.[8] Given the rapid expansion in use, and touted promise of these devices for improving both clinical and psychosocial outcomes, it is critically important to understand issues in technology adoption, equity in access, maintaining long-term usage, opportunities for expanded device benefit, and limitations of the existing evidence base. The purpose of this article is to provide a brief overview of

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the evidence, clinical application, and future directions of diabetes technologies. We have focused specifically on psychosocial outcomes and provide recommendations for future work and considerations in clinical applications.

How are Benefits of Technologies Defined?

Early efficacy studies of these technologies focused nearly exclusively on the improvements in glycemic control, as measured by changes in hemoglobin A1c; while subsequent work has turned our attention toward the potential of these devices for reducing the emotional burden of the daily management of diabetes, the user experience, and related changes to key psychosocial constructs. Despite compelling evidence of the glycemic benefits of these technologies, research on the psychosocial impact has been mixed. Conceptually, such mixed findings may be expected, as diabetes technology can alleviate task-specific burdens and related distress (such as frequent daily blood glucose monitoring in the case of CGMs and multiple daily injections in the case of insulin pumps) and provide important opportunities for real-time, fine-tuned adjustments in dosing (such as time-varying and fractional insulin ratios with an insulin pump and automated correction doses with AID systems). These systems may also exacerbate diabetes distress due to common alerts and alarms (implemented for safety reasons and often outside of user control regarding frequency, timing, and noise level), the necessity of wearing large, electronic devices that are physically affixed to a body nearly around the clock, and the startup and continuation cost of acquiring these devices (eg, the need for specialty pharmacies to fill orders, and the time required to complete insurance paperwork and prior authorizations for durable medical equipment in United States contexts). Collectively, these burdens can affect not only daily diabetes distress, but also sleep quality, self-confidence and perception, ability to effectively utilize the devices, financial burden, and several other inter-personal and intra-personal concerns.

Indeed, these negative aspects of device use are reflected in empirical work[9] that attributes them to device discontinuation and barriers to initiation. Of those discontinuing CGM use in a large registry study, 32% were bothered by alarms, a further 20% to 30% perceived the device to be inaccurate or reported a general mistrust of the device, and 29% felt that the CGM took too much time and effort to use. Even among current CGM users, 47% reported the hassle of wearing the device was a barrier for continued use. Divan et al[10] found that participants expressed concerns related to the cost of the devices, the physical discomfort related to using the device, and a sense of not trusting the data. Similar findings related to perceived barriers have been reported in studies assessing the perceptions of parents of young children[11] and of teenagers.[12] Perceived benefits of technologies have also been assessed in these studies, with participants reporting technology use makes caring for diabetes easier,[10] decreases parents' worry, increases their sense of safety, and improves their sleep,[11] and that teens appreciate being able to have access to their data including trend arrows to inform their next steps.[13]

In recent years, more research in diabetes technology has assessed person-reported outcome data and measures of psychosocial impacts. Although findings across studies have been mixed, positive results have been shown in several studies. For instance, CGM and AID use has been attributed to improvements in diabetes-specific emotional distress,[14-24] reductions in fear of hypoglycemia,[17,19,24-27] improvements in sleep quality,[17,19,28-31] improvement in quality of life,[24,30,32-34] and increased treatment satisfaction.[14,23,28,30-33,35,36] There is a conflicting evidence base that has shown null findings across many of these outcomes[14,17,18,20,23-25,27,31,32,34-41]; importantly, there is no evidence that technology use contributes to a worsening of psychosocial status for the majority of people. A minority of studies have sought to explain differences in the impact of technology use on psychosocial outcomes by examining potential effect modifiers,[21] but this remains a substantially under-investigated area of research.

Assessing the psychosocial impact of diabetes technology is necessary as the success of these technologies is predicated upon whether the user finds more benefits than burdens[20,27] and is therefore willing to not only try the device, but also continue using it. For example, while there is a wealth of evidence demonstrating that CGM devices can be associated with increased self-efficacy in diabetes self-management through immediate feedback of blood glucose levels and trends, this is not the case for all. Unfortunately, they also have the potential to increase learned helplessness as people with diabetes report that whatever they do in terms of self-management is never enough[42]; and national diabetes audit data show stubbornly sub-optimal glycemic result data year on year, despite the growing use of diabetes technologies.[43]

Device manufacturers are consistently iterating on the design and features of these devices and may be able to address some of the concerns identified as barriers to use but it is unlikely that all potential concerns will be addressed on a short time scale. In the interim, it will be critical for providers to collaborate with each individual patient, work to match the demand characteristics of each system with that person's needs and expectations, and clearly discuss both the potential benefits and the potential downsides when using each system, particularly during onboarding, to mentally and emotionally prepare patients for the realities of device use. In order for people with diabetes and their loved ones to achieve satisfaction and the desired positive results from the use of diabetes technologies, they must perceive the benefits outweigh the burdens. This is particularly relevant since each system currently on the market varies with respect to both the system features and functionality, and the level of interaction with the system needed by the user. Currently, the

systems differ[44] with respect to the hardware (the pump and the CGM system that is used), the alarm burden, the degree of user input required for system functioning, the ability of the user to adjust the algorithm, and the ability of the system to compensate for changes in work/life demands (such as shift work).[45] A personalized experience with each system will be predicated on the match between an individual's preferences, needs and expectations of a system,[46,47] and each system's specific features and functionality.

This discrepancy between individuals' expectations for reduced behavioral demand and the reality of the need for continued engagement in self-management behaviors has emerged in recent studies of AID devices. A clinical trial in adults 60 years of age and older found reduced fear of hypoglycemia as well as decreased psychological burden and improved sleep with use of this technology.[48] However, although participants reported reduced daily effort with AID in structured interviews, they also expressed disappointment that the system did not act more like a healthy pancreas and required more effort on their part then they had expected. These reports were consistent with the questionnaires completed by these older adults before and after the trial, which showed positive expectations for AID before use and, after use, continued positive reactions but a decrease in the degree of positivity. As noted above, setting realistic expectations for users is a critical part of education for onboarding to AID devices. This includes information about the continued need for meal and correction boluses for some of the current systems, as well as strategies for avoiding over-treatment of hypoglycemia and hyperglycemia.[3] A recent real-world data set of over 19 000 AID users examined glycemic outcomes during the first three months of use of the system.[49] For those individuals whose average number of daily self-administered meal and correction boluses stayed consistent with pre-AID use, average time in range achieved was 84%. In contrast, those who showed a decrease in daily self-initiated meal and correction boluses achieved a much lower average time in range of 54%. These findings demonstrate that, at least with some hybrid closed-loop systems, achieving optimal glycemic outcomes remains dependent on the behavioral effort of the user.

Onboarding: Timing and Content

Unfortunately, very little research has examined the process of onboarding to new technologies and how this experience contributes to continuation or discontinuation of technology usage. There is no evidence base for the development of programs to educate and support individuals during the early stages of use. The available evidence for AID systems suggests that early device use, specifically time spent in Auto Mode, is a predictor of longer-term success with these technologies.[50] Another study of discontinuation of an open-source AID system found that difficulties learning to use the device effectively were predictive of discontinuation.[51] A subsequent study found that, six months after initiating use of these systems, reported difficulty during onboarding was associated with poorer psychosocial outcomes, including more diabetes distress in adults, increased fear of hypoglycemia in children, and poorer sleep quality in both children and parents.[52] These finding suggest that, after initial onboarding, individuals should be monitored for difficulties in the early stages of adaptation and receive increased education and/or support when problems are experienced. More extensive research is needed to assess the different types of support individuals need during the early phases of technology use, and this information must come from the users themselves and their families/caretakers.

Marginalized Groups and Inequality

As mentioned, we may conceptually expect mixed results regarding the psychosocial impact of diabetes technology, but there are several important limitations and potential biases in this research that also need to be considered when contextualizing the findings. Many of the studies are subject to considerable selection biases whereby well-resourced groups and those with already low to moderate levels of diabetes distress are disproportionally represented. Specifically, of the eight definitive hybrid closed-loop clinical trials in the United States, only 6% and 2.2% of the enrolled individuals were Hispanic and non-Hispanic black, respectively[53]; considerably less than the racial-ethnic prevalence of T1D.[54] This reflects broader disparities in access and uptake of diabetes technologies. Taking continuous glucose monitoring systems, for example, a retrospective chart review of 1509 T1D children found that a significantly higher percentage of white (54%) patients were started on CGM compared with black (31%) and Hispanic (33%) patients ($P < .001$).[8] In a retrospective review of 227 adult T1D patients who were seen in an urban, safety-net endocrinology clinic, investigators found that only 85 patients (37%) used any diabetes technology.[55] Within this cohort, a significantly higher percentage of white patients (55%) used CGM and/or insulin pumps compared with black (28%), Hispanic (28%), or other ethnicities (24%). A significantly lower percentage of black (4%) and Hispanic (9%) patients used both technologies compared with white (35%).

Barriers to technologies among marginalized and economically disadvantaged groups include mistrust of health systems, lack of support, financial constraints, provider biases, stigmatization, stringent insurance policies, and clinical infrastructure.[56] Such inequalities can be overcome by improving awareness, refining and adhering to equity-focused policies, and emphasizing personalized patient-centered approaches to health care delivery. In addition, making access to health care more equitable requires acknowledgment and understanding of social determinants of health (SDOH) and their mutability. For example, while some SDOH are immutable, others, such as inequity in

power, money, and resource (eg, affordability of drugs), can be addressed with targeted health policies. Ultimately, the exclusion of historically marginalized groups who are the least likely to have access to diabetes technology[57,58] reveals a blind spot in our understanding of the distribution of psychosocial burdens of diabetes technology and effective strategies to mitigate them while simultaneously addressing equity concerns.[59-61]

Measurement Issues

There are considerable differences in the psychosocial constructs that are measured across studies, both in terms of underlying constructs addressed (eg, depression versus diabetes distress) and general versus disease-specific measures. While variability in assessed outcomes is important to capture the potential range of effects, in many cases, psychosocial measures are included as secondary (or tertiary) outcomes without consideration of potential causal mechanisms that may link use of diabetes technology to specific psychosocial consequences. In addition, clinical trials are typically not statistically powered to detect significant changes in patient-reported outcomes, which likely contribute to the inconsistent and mixed findings on psychosocial impact. Finally, very few studies specifically look at mechanisms linking outcomes to specific components of diabetes technology, ranging from the device level (pump vs CGM) to the feature level (device size vs alarm configuration). These types of mechanistic inquiries are critically important to direct interventions designed to alleviate device burden and ultimately help patients maximize the potential benefit of their devices.

In addition, clinical trials assessing psychosocial outcomes with self-report measures typically analyze these data at the group level, comparing the control and experimental conditions at critical time points. Such an approach can obscure important information. An example of this is a recent large clinical trial of an AID system that found significant group effects in psychosocial variables, including decreases in diabetes distress, quality of life, stress, anxiety, and fear of hypoglycemia.[62] However, in spite of these group improvements, at the end of the study, 50% of the adults in the AID group still reported clinically severe levels of diabetes distress. These findings point out, not only the value of examining psychosocial outcomes beyond the level of statistically significant group differences, but also the important fact that use of technology will not necessarily eliminate the emotional distress and burden associated with living with diabetes. More research is needed that focuses on individuals who are struggling emotionally and behaviorally to cope with the negative impact of diabetes on their lives, such as those with severe levels of diabetes distress or glycemic instability, and how to leverage diabetes technologies to improve their quality of life and medical outcomes.

Another method that can obtain information and insight beyond group comparisons is the structured interview to gather qualitative data from individuals using diabetes technology.[48,52] An early study using this methodology interviewed individuals both before using AID and after using the system for three months.[63] Despite positive expectations for AID use, participants reported that it took several weeks to develop full trust and confidence in the device. Positive psychosocial benefits included a decrease in emotional, mental and behavioral burden, and improvements in relationships, especially between parents and children, due to decreased parental monitoring and reminders related to diabetes-related tasks. Parents of younger children reported an increased feeling of safety and decrease in the need to be overly vigilant, which in turn allowed them to give their child more freedom to be away from them for age-normal activities, such as playdates and sleepovers. This type of insight into the effects of diabetes technology on family dynamics is difficult, if not impossible, to capture using standardized questionnaires.

Clinical Considerations and Conclusions

The numerous remaining questions about psychosocial impact notwithstanding, these devices can be life-changing for many living with diabetes, and so it is imperative that practitioners prioritize understanding, communicating, and addressing the sometimes-conflicting forces that can promote or dissuade diabetes technology use among their patients. While there are no formal tools available to assist providers with assessing patient and family perceptions around benefits and burdens of technology, we strongly encourage an open conversation about the range of experiences with these devices that includes a nuanced discussion of possible misperceptions and sets realistic expectations for physiological and psychological outcomes. With sufficient support from the diabetes care team, individuals may be more likely to initiate and persist in their use of these technologies, and thus reap demonstrated benefits in glycemic outcomes. Additional research that fully explores effect heterogeneity in the ways in which diabetes technology can impact psychosocial outcomes will be critical for personalizing strategies to optimize technology use among individuals. Utilizing a core set of patient-reported psychosocial outcomes, harmonized across future studies, as well as seeking to recruit maximally diverse samples of participants (with regards to both sociodemographic and clinical characteristics), should be critical goals for future research to optimize investigator's ability to evaluate important effect heterogeneity.

Substantial evidence supports the promise of diabetes technology for improving both glycemic and psychosocial outcomes. Despite the wealth of the existing literature exploring the latter effects, there is substantial room to expand our current knowledge base to more comprehensively address

reasons for differential effects. This information will prove critically important for establishing best practices for practitioners in supporting patients who choose to use these devices.

Abbreviations

AID, automated insulin delivery; CGM, continuous glucose monitors; T1D, type 1 diabetes.

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