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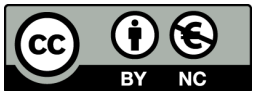

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Clinical Usage and Potential Benefits of a Continuous Glucose Monitoring Predict App

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Abstract

Continuous glucose monitoring (CGM) has become an increasingly important tool for self-management in people with diabetes mellitus (DM). In this paper, we discuss recommendations on how to implement predictive features provided by the Accu-Chek SmartGuide Predict app in clinical practice. The Predict app's features are aimed at ultimately reducing diabetes stress and fear of hypoglycemia in people with DM. Furthermore, we explore the use cases and potential benefits of continuous glucose prediction, predictions of low glucose, and nocturnal hypoglycemia.

Keywords

quality of life, rtCGM, glucose prediction, diabetes self-management, hypoglycemia, diabetes distress

For people with diabetes mellitus (DM), the fear of hypoglycemia is a substantial burden and a major cause of diabetes distress.[1,2] Today's continuous glucose monitoring (CGM) systems provide a real-time view on glucose levels to reduce these strains to a certain extent.[3,4] However, the CGM functions for glucose prediction that are currently available are limited to trend arrows with a restricted forecast horizon and predictive alerts with fixed thresholds.[5-7] Thus, the unpredictable nature of glucose levels remains.[3,4]

A survey by Ehrmann et al, which is published in the same special issue of this journal, presented novel extended glucose prediction features to participants with DM as hypothetical scenarios. The results showed that using a CGM device with such prediction features, people with DM anticipated a reduction in fear of hypoglycemia and diabetes distress as measured by the Hypoglycemia Fear Survey (HFS-II) and T1 Diabetes Distress Scale (T1-DDS).[8] Therefore, the perception of an extended glucose prediction for people with DM was positive and suggests predictions such as these have the potential to reduce the diabetes-related burden for people with DM in their everyday lives.

With this in mind, the Accu-Chek SmartGuide Predict app provides three newly designed artificial intelligence–enabled glucose prediction features in addition to the associated real-time continuous glucose monitoring (rtCGM) Accu-Chek SmartGuide (both Roche Diabetes Care GmbH, Mannheim, Germany). It contains a customizable 30-minute low-glucose prediction, a continuous 2-hour glucose forecast displayed as a curve, and an adjustable 7-hour prediction of nocturnal hypoglycemia.

Advice for Clinical Practice

The Predict app is intended for people with DM on a flexible insulin regimen such as multiple daily injection (MDI) or continuous subcutaneous insulin infusion (CSII) therapy. It is used in combination with the Accu-Chek SmartGuide CGM device and the Accu-Chek SmartGuide app. All features are validated for both insulin-treated people with type 1 diabetes (T1D) and type 2 diabetes (T2D).[8] A full feature description as well as performance data can be found in the

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article by Herrero et al[9] and the Technology Report by Glatzer et al[10] in the same special issue of this journal.

Low-Glucose Predict

The Low-Glucose Predict (LGP) feature detects and alerts users if there is a high risk for low glucose within the next 30 minutes based on data from the CGM sensor and, if logged, the last carbohydrate intake.

What's the goal? The desired goal of the LGP feature is allowing people with DM acting proactively and impeding a hypoglycemic event from happening in the first place or reducing its length and intensity.
How to set LGP up? LGP is active by default and can be deactivated in the app. Users can set the glucose threshold values used by the LGP feature individually in the range of 60 to 100 mg/dL (3.3-5.6 mmol/L). This individualization of low-glucose prediction thresholds has not been available in existing CGM solutions yet.[11-13]
How to react? LGP is continuously updated every 5 minutes, and patients can use the information for immediate action in order to prevent hypoglycemic events. In case of notification, users should verify the situation and follow, if needed, the recommendation to take in 15 g carbohydrate.
Impact on whom? Generally, all people with DM on a therapy regime, which can lead to hypoglycemia can benefit from using LGP. In particular, LGP can help individuals with hypoglycemia unawareness, as well as individuals with fear of hypoglycemia who tend to maintain constantly higher glucose values to avoid hypoglycemia or even refrain from certain activities because of hypoglycemia. Also, individuals with frequent hypoglycemia and individuals who plan situations that might become critical if hypoglycemia happens such as a car ride can benefit from the feature.

Glucose Predict

The Glucose Predict (GP) function provides and visualizes a robust continuous 2-hour glucose estimate based on historical glucose levels available in the CGM system, logged app data (carbohydrate intake, insulin administration), and the time of day.

What's the goal? The desired goal of the GP feature is to provide users with predicted glucose levels for the upcoming 2 hours in order to improve self-efficacy and make informed decisions about insulin dosing, physical activity, or diet.
How to set GP up? GP is active by default. The graph visualizing the predicted glucose course is visible on the home screen of the Predict app.
How to react? Action upon the predicted 2-hour glucose course depends on the time window. The prediction covering the next 45 minutes can be used to take direct measures. The right moment to act will depend on the actual context. This includes the time when the glucose level is predicted to be high or low and the timely effect of the chosen action like insulin administration, carbohydrate intake, or physical activity. Predictions covering the time beyond 45 minutes shall be used to raise awareness and allow users to have more preparation time without the need for immediate action.
Impact on whom? GP updates every 5 minutes and can be used for immediate action within regular diabetes management, for awareness, or for information, like prior to activities where the users need to anticipate glucose excursions. These include avoiding hypoglycemia in potentially risky situations such as working on a ladder or social situations. Also, individuals with hypoglycemia unawareness, individuals with fear of hypoglycemia or hyperglycemia who typically apply avoidance strategies or limit their activities, and individuals with frequent hypoglycemia can benefit from glucose prediction.

Night Low Predict

The Night Low Predict (NLP) feature estimates the individual risk of low-glucose levels ($<$70 mg/dL; $<$3.9 mmol/L) within the following 7 hours during the night or in the first or second half of the night, respectively.

What's the goal? NLP allows users to understand their individual risk for nocturnal hypoglycemia in the upcoming night and to take preventive actions before going to bed, allowing for a restful and undisturbed night.
How to set NLP up? NLP is active by default and can be deactivated in the app. Users can personalize their bedtime, which sets up when the prediction for nocturnal hypoglycemia risk is being generated and a notification is being sent out in case of elevated risk.
How to react? Using a prediction indicating a high risk of nocturnal hypoglycemia enables individuals to make informed decisions and take appropriate actions during the night. This can also include reassessing glucose levels during these instances. Although general recommendations for management of nocturnal hypoglycemia are well known by health care providers (HCPs) and depend on the individual treatment goals, an individual risk for the upcoming night may open up more nuanced recommendations. For hypoglycemia in the first half of the night, the intake of carbohydrates is an option. For hypoglycemia in the second half of the night, a mixed nutrient meal containing both fat and protein should be considered.[14,15]
Impact on whom? Individuals with frequent nocturnal hypoglycemia and individuals with fear of nocturnal

hypoglycemia as well as individuals who regularly aim to keep their glucose levels higher to avoid nocturnal hypoglycemia can specifically benefit from this risk prediction.

Discussion

People with DM can benefit in many ways from the Predict app's features described above. However, some general conditions should be taken into account.

The underlying algorithms have been trained on population data using machine learning techniques to identify the most relevant correlations between the respective input data and prediction output of interest. Nevertheless, it is important to emphasize that individual predictions are based on individual data. The personalization is achieved by including inputs into the algorithms that are based on both current and retrospective individual data for up to 28 days and a range of customizable settings. A detailed feature description is provided by Herrero et al.[10] Users can gain insights into future glycemic profiles and thus raise their awareness for their individual glucose patterns as well as improve preparedness for glucose excursions. However, the predictive algorithms do not consider future user actions that may impact glucose levels. For example, the algorithms cannot anticipate the consumption of a meal in an hour.

Therefore, users need to be aware of these aspects in order to accurately interpret the predictions. To ensure a high performance of the glucose prediction in the postprandial phase, users need to log carbohydrates and insulin at mealtimes. Not doing so results in a lower prediction performance in the immediate postprandial phase. As soon as actions like carb intake or insulin administration become noticeable in the glucose excursion, they also influence the prediction, as the predictions are continuously updated. As the predictive features are cloud-based, they require Internet access to continuously generate the predictions (glucose values and risk assessment for hypoglycemic events). However, the basic functions and alerts of the accompanying CGM solution work offline and independently of the Predict app.

Exploring the potential of machine learning in diabetes self-management is crucial, considering its impact on individuals. The results of the glucose predictions can have a complex psychological impact that may differ significantly from person to person. Therefore, it is important that people with DM collaborate closely with diabetes care teams for ongoing support, empowerment, and personalized feedback to address these complexities and foster a balanced approach to integrate predictive algorithms into diabetes management strategies. A clear understanding of the limitations of the algorithms is prerequisites for taking direct actions based on these predictions.

Taking into account the limitations described above, the Predict app can provide valuable support for people with DM.

The growing availability of glucose data, trends, and alerts is valuable in reducing uncertainty and has already been linked to enhanced emotional well-being among users, particularly individuals who experience high levels of fear of hypoglycemia.[16,17] Trend arrows are widely used by people with DM in their self-management. However, they only cover a timespan of about 15 minutes and thus do not provide a comprehensive and accurate overview of future glucose. Moreover, these trend calculations are only influenced by the most recent history of glucose levels.[5-7] By contrast, the 2-hour glucose prediction is based on a machine learning algorithm that takes an array of input factors into account, like time series and time series aggregates of CGM readings, aiming for an improved prediction quality. In addition, the prediction of future glucose development goes beyond the period covered by trend arrows.

Furthermore, the visualization as a curve appears much more user-friendly and easier to comprehend. This can prevent overreactions, especially based on fear of hypoglycemia.[5,18-21] With this in mind, glucose prediction can be seen as an evolution of trend arrows with a more differentiated approach. Actively using a 2-hour glucose prediction and the 30-minute LGP can help to spare the often socially aversive and intrusive audible alarms in public. Alarms are something users want to avoid, as they can signal rather negative aspects of DM such as impending risks, danger, or perceived failure and have the potential to add to diabetes stigma. These can lead to avoiding self-management measures in public with subsequent suboptimal glycemic outcomes.[8,14,21] By lowering the alarm frequency, it can also have a beneficial effect on alarm fatigue, which is not uncommon in people with DM using CGM.[22,23]

Feeling powerless to control glucose and glucose variability serves as a major source of diabetes distress.[2,24,25] Therefore, glucose prediction as well as low-glucose prediction features aim to mitigate diabetes distress. The LGP particularly aims to address distress associated with hypoglycemia and consequently target possible complications such as hypoglycemia recurrences and unawareness, accidents, or exacerbation of secondary diseases due to fluctuating glucose levels.[8] Moreover, the users could benefit from the feature's high 99% specificity that may help prevent alarm fatigue, and from its high 95% sensitivity that could support not missing hypoglycemia and thus feeling safe.[8,10] In the respective in silico simulator data, continuous glucose levels of 10 adults with T1D were physiologically simulated. The model included the immediate action of 15 g carbohydrate intake upon an LGP notification. After 30 simulated days, the time below range $<$70 mg/dL was reduced by 92% compared with not using low-glucose notifications and by 47% compared with using classical hypoglycemia threshold alerts.[26] Furthermore, people with DM desire personalization and being able to tailor their use of diabetes technology to best support their daily diabetes management.[21] The opportunity for low-glucose prediction threshold individualization

may be beneficial, as it can be used as a safety-net throughout the day in various situations, aiming to allow a better planning of activities and diabetes management decisions.

Nocturnal hypoglycemia has also been identified as a significant problem for people with DM and is associated with disruptions caused by devices and additionally with considerable clinical impact. In addition, nocturnal hypoglycemia involves high socioeconomic burdens and costs such as loss of productivity at school and work as well as health care resources required to treat hypoglycemic events.[27-29] The burden of nocturnal hypoglycemia is comprehensively described by Kulzer et al[28] in a publication in the same special issue of this journal.

Going to bed with an estimate of one's personal risk for nocturnal hypoglycemia can improve the feeling of control, empowerment, and safety. This can reduce the distress and fear of nocturnal hypoglycemia as indicated in the survey by Ehrmann et al.[8]

Existing data show that combining the prediction of nocturnal glucose with proactive recommendations for bedtime carbohydrate or mixed nutrient intake can prevent hypoglycemia during the night and ease the burden of glycemic self-management.[14,15,30] In line with these data, in silico simulator testing of the NLP algorithm demonstrated a mean reduction of nightly time below range (<70 mg/dL) by 37% from baseline (continuous glucose levels of 10 adults with T1D were physiologically simulated for 30 simulated nights. The model included the immediate action of 15 g carbohydrate intake upon an NLP notification).[26] This indicates that proactive management of nocturnal hypoglycemia may lead to less interruptions of sleep and less negative health impact. This can, in turn, contribute to sleep quality and to overall health.[14,28]

In conclusion, the potential benefits of novel CGM algorithm–based glucose predictions in daily diabetes management are significant, holding promise in positively impacting the well-being of individuals with diabetes. Nevertheless, further research is needed to validate these outcomes associated with glucose prediction. This will be even more applicable when the Predict app is on the market and data from a real-world setting are available. It is vital to generate sound evidence based on retrospective and prospective studies. Therefore, various in silico and clinical trials as well as real-world data analyses are ongoing or planned. With this, Roche is committed to provide comprehensive scientific and clinical evidence for the benefits of glucose prediction.

Abbreviations

CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; DM, diabetes mellitus; HCP, health care provider; HFS-II, Hypoglycemia Fear Survey II; LGP, Low-Glucose Predict; MDI, multiple daily injection; NLP, Night Low Predict; PRO, person-related outcome; rtCGM, real-time continuous glucose monitoring; T1D, type 1 diabetes; T1-DDS, T1 Diabetes Distress Scale; T2D, type 2 diabetes

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Declaration of Conflicting Interests

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