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ORIGINAL ARTICLES

Analysis of the Performance of the Software/Hardware Product MyDiaBase+RxChecker for Assessing Treatment Regimens

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Abstract

In 2008, the Action to Control Cardiovascular Risk in Diabetes trial was halted due to an unexpected number of deaths in the intensive treatment group (aiming for hemoglobin A1c levels less than 6%). Hypoglycemic episodes were thought by some to be a contributing cause, underscoring again the challenge of maintaining tight control while avoiding dangerous excursions into hypoglycemic territory. Albisser and colleagues present a set of articles in this issue of *Journal of Diabetes Science and Technology* that describe a clinical product developed specifically for this timeless clinical conundrum.

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Introduction

It has been nearly a century since the identification of the pancreatic beta cell as the source of insulin and dominant regulator of glucose metabolism. The task of replacing the natural physiological scheme of insulin secretion for the diabetes mellitus (DM) patient has been a central theme. As it is with much of clinical medicine, the challenges of treatment reside in our attempt to understand the full complexity of the biology while concurrently developing practical clinical strategies. Diabetes mellitus typifies this challenge. The past two decades have yielded unprecedented advances in cell and molecular biology as well as significant unraveling of DM pathophysiology. In addition, clinicians have an expanded array of therapeutics and diagnostics to monitor disease evolution. In parallel, there have been remarkable advances in technology that have enabled the miniaturization of data collection, storage, and computation.

In this issue of *Journal of Diabetes Science and Technology*, Albisser and associates exemplify the convergence of medicine science and technology in their approach to one of the most critical clinical issues in the treatment of DM: hypoglycemia. In an article featured in the Technology Reports section, Albisser and coworkers describe a product they have developed over several

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Abbreviations: (ACCORD) Action to Control Cardiovascular Risk in Diabetes, (HbA1c) hemoglobin A1c, (DM) diabetes mellitus

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years that enables patients and their providers a more detailed examination of the daily treatment and glucose monitoring cycle than is currently feasible in most outpatient settings. The device/product is made up of two components: a patient database (MyDiaBase) that is mostly patient input driven and a RxChecker program that assists and displays an analysis of the patient outcomes, all contained in a standard USB flash drive.[1] With this device, the patients are charged with the responsibility of inputting personalized data, including demographics, self-monitoring blood glucose measurements, body mass index, exercise, and medications. The procedures and device description are outlined very clearly in the article entitled, "Closing the Circle of Care with New Firmware for Diabetes: MyDiaBase+RxChecker."[1] The provider component enables the clinicians to assess the current treatment regimens and graphically inspect to see whether the regimen is performing within the treatment guidelines that have been outlined. When the performance is outside the guidelines, the clinicians are able to use a built-in physiological model-based simulator that will predict blood glucose results for any potential changes in treatment or diet they are contemplating. The importance of this closed-loop approach for the brittle and hypoglycemia-prone DM patient cannot be overemphasized. In 2008, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial was halted due to a statistically unexpected outcome in the intensive treatment group [aiming for hemoglobin A1c (HbA1c) levels less that 6%]. As noted by Albisser's group, hypoglycemia could have been a contributing element, as implied by the treatment target of "normal" HbA1c levels, thus underscoring the difficulty of maintaining tight control without avoiding hypoglycemic episodes.

To further prove this concept, Albisser and colleagues, in another article titled "Prescription-Checking Device Promises to Resolve Intractable Hypoglycemia" in the Original Articles section of this issue, tested their device on 11 type 1 DM patients.[2] These patients all suffered from recalcitrant hypoglycemia and were placed on intensified therapy as described in the ACCORD study.[3] The results showed that, of the 822 profile points explored, 43% showed risks of hypoglycemia defined by the glycemic targets of the providers. Albisser and associates then used the glucose prediction simulator to see what the effect of treatment intervention (at one or more points) would do for the overall glycemic control. The results demonstrated that the predicted risks of hypoglycemia were reduced 2.5-fold while the overall HbA1c was not statistically changed.

Clearly, there are many vulnerabilities that remain in the current model. The data have to be faithfully inputted by the patient, and therefore, compliance is still required. The frequency of checking by the providers may vary from patient to patient and even within the same patient. The system has to be personalized, and prospective studies on a larger scale must be performed to validate and test the features. The glucose predictor model may have to be modified or adapted for wider range of physiological/clinical conditions. Many physiological models exist,[4] and one can foresee a situation where the model chosen is modular and part of the device software. The wish list would include automation of many features and perhaps a continual telemedicine feed between the provider and the patient. All these are but details that can be refined and built on the fundamental framework developed by Albisser *et al.*[2] The contribution to the clinician dealing with these management issues is significant and is a major step in dealing with a longstanding clinical challenge.

Albisser and colleagues are not alone in attempting to develop this type of clinical tool. In Europe, a €7.1 million/4-year grant was issued to fund the development of the portable DIAdvisor™ system incorporating a wireless body monitoring technology for improved DM management.[5] The large-scale project is being coordinated by Novo Nordisk A/S and will be delivered by a consortium of 13 medical, industrial, and academic partners, including the European region of the International Diabetes Federation. As in the Diabase system, the DIAdvisor system utilizes physiological inputs (from nonintrusive body-worn wireless monitors) and predicts blood glucose levels based on glucose measurements, insulin delivery data, and specific patient parameters. Both devices aim to enable DM patients to achieve optimal insulin therapy and take other proactive measures to regulate glucose levels, such as nutrition and exercise, with the goal of reducing the risk, occurrence, and treatment costs of hypoglycemic events and the complications that arise from chronic poorly controlled blood glucose.

In the current health care delivery crisis, now further complicated with a global economic slowdown, solutions that enable disease management and enhance prevention are increasingly needed and welcome. The work by Albisser and associates is a model to be carefully studied.

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