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ORIGINAL ARTICLES

Analysis of GlucoMen®Day: A Novel Microdialysis-based Continuous Glucose Monitor

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Abstract

In this issue of *Journal of Diabetes Science and Technology*, Valgimigli and colleagues present promising data on the clinical accuracy of the new microdialysis-based continuous glucose monitoring device GlucoMen®Day. In this analysis, two issues are addressed: first, the established way data analyses may obscure interindividual variability in terms of a glucose monitoring system's accuracy; and second, to fully appreciate the future merits of the new system, data on accuracy, while a clearly necessary prerequisite, are not sufficient and need to be augmented by patient-reported outcome data as highlighted by recent U.S. Food and Drug Administration guidelines.

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Back in the early 2000s, the first papers on the GlucoDay glucose monitoring system developed by A. Menarini Diagnostics were published, and the device hit the European markets soon after. It has taken quite a long time for details of the successor device to be revealed and for data to be published.

The article by Valgimigli and colleagues[1] in this issue of *Journal of Diabetes Science and Technology* focuses on the GlucoMen®Day's accuracy and demonstrates good measurement properties under a variety of conditions that exceed the performance of its predecessor using state-of-the-art approaches in the field. Valgimigli and colleagues[1] further present data on time lag between blood glucose and interstitial monitoring readings and appropriate data-analytic procedures to compensate for time lags. Reading their report, two things came to my mind that, in my view, have to be considered if one wants to fully appreciate the clinical utility of the device. One concerns the way accuracy issues are addressed, and one revolves around necessary steps following the studies that are presented in their article.

Concerning the issue of accuracy, Valgimigli *et al.*[1] employed standard state-of-the-art procedures as recommended by applicable guidelines, e.g., the continuous error grid analysis and standard indices of accuracy. The overall correlation between sensor glucose and reference measurements, perhaps the most common measure of accuracy, is high. I have argued before that computing indices, such as Pearson's correlation, over aggregate data necessarily obscure interindividual variability in accuracy. Those working with continuous glucose monitoring in clinical practice know that varying reliability of measurement across patients can be an issue. Within-subject data are statistically dependant measurements (measurements nested in subjects), and a mixed regression approach would be the most appropriate

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to quantify interindividual variation of reliability. This could easily be done, and respective analyses could add to what can be learned from aggregate data accuracy, given that aggregate data analysis may obscure relevant findings, as the data structure is neglected (that is, independence of measurements is assumed). This criticism holds not only for their article (with $N = 12$, analyses on interindividual variability could be difficult but still doable; at least, the amount of interindividual variance could be quantified), but for most papers on the accuracy of continuous glucose monitoring systems in general.

My second point revolves around another issue. Valgimigli and colleagues demonstrate good accuracy of the new system. I posit that more has to be known—in addition to the system's accuracy—in order to appreciate the merits of the device fully from a clinical perspective. It has to be noted that the GlucoMen Day, at present, is still one of the few glucose monitoring devices around that are based on microdialysis, with its inherent advantages (and disadvantages) compared to the more common needle-type sensors. Due to its measurement rationale, microdialysis-based systems cannot be miniaturized to the size that needle-type sensors are nowadays and also have to rely on multiple components (such as some kind of waste compartment to hold the buffer solution pumped through the interstitial tissue). One of the major drawbacks of the GlucoDay, the GlucoMen Day's predecessor, lies in patients' acceptance and the discomfort experienced while wearing the device, which has been documented previously.[2]

The GlucoMen Day system seems to be particularly promising in this respect. As shown in the article by Valgimigli and colleagues[1] and details that have been released previously, the new device seems to have been improved considerably. The dimensions of the GlucoMen Day are much smaller than the GlucoDay. The new system is indeed compact, and I wonder if a microdialysis-based system could be reduced in size any more at all. I also highly appreciate that the display and control unit has been detached from the actual monitoring device by means of a hand-held computer. Apparently, a lot has been done to overcome obvious shortcomings of the device's predecessor. However, data on patients' acceptance of the system were not presented. I agree that, first, adequate reliability of a method has to be demonstrated. Data on the logical second step—the feasibility of the application, as indicated, for instance, by the patients' acceptance—are often missing (or at least not published). This solely accuracy-focused narrow view on novel measurement devices, in fact, seems a bit puzzling to me, as all devices are designed for clinical applications in real life (from this perspective, I highly welcome the real-life approach outside the laboratory of the study by Valgimigli and colleagues[1]).

Interesting things in this regard may be learned from a statement by the Food and Drug Administration[3] that clearly states the necessity for data on patient-reported outcomes that are, at best, captured under "real-life" conditions (compare with Reference 4). In my view, this also holds for medical devices. Published papers should not detach results on the device's performance from so-called "soft" criteria, such as how well the patients get along with using the device or the ease with which a health care professional can handle it. Results in both domains are crucial.

The results reported by Valgimigli and colleagues[1] thoroughly demonstrates the system's measurement capabilities in terms of accuracy and reliability. Both were also strengths of its predecessor. However, more data on patients' acceptance in terms of patient-reported outcomes and data on performance in a "real-life" clinical setting will be crucial to fully appreciate the value of the GlucoMen Day.

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