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Commentary Regarding Shapiro, "Nonadjunctive Use of Continuous Glucose Monitors for Insulin Dosing: Is It Safe?"

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Abstract

The FDA recently expanded the approved use of Dexcom's G5 Mobile continuous glucose monitoring (CGM) system to allow for diabetes treatment decisions. This decision is expected to reduce the burden of SMBG testing and increase the adoption and persistent use of CGM. The safety of nonadjunctive CGM use was questioned because of sporadic large discrepancies between CGM and SMBG values. These data were viewed in the context of complaints found in the FDA MAUDE database and social media postings. This commentary provides additional perspective on the inferences that can be drawn from these reports and the risk of nonadjunctive use of CGM data.

Keywords

continuous glucose monitoring, nonadjunctive use, self-monitored blood glucose, FDA decisions

I read with interest the recent commentary regarding the safety of nonadjunctive use of continuous glucose monitoring (CGM) data for insulin dosing,[1] and the now-resolved question[2] of whether this use should be included among the labeled indications for the Dexcom G5 Mobile CGM System. Although I agree with some of the points made, I feel that several issues regarding device accuracy and the way in which CGM data are presented and used have not been sufficiently addressed.

Nonadjunctive Use of CGM

First, the accuracy of self-monitored blood glucose (SMBG) data deserves further scrutiny, and the possibility (and consequences) of egregiously inaccurate SMBG readings deserve acknowledgement. Current-generation SMBG devices perform well under ideal conditions.[3] In the real world, however, deviations from best handwashing practices are common,[4] and even under supervised conditions, many patient-owned SMBG devices do not meet ISO 15197 criteria.[5] There are tens of thousands of inaccuracy complaints in the MAUDE database against meters—most of which are unsubstantiated, highlighting one of the limitations of the database.

Second, the focus on inaccuracy of selected CGM readings neglects the quantitative and qualitative differences between SMBG and CGM data. From the standpoint of data quantity, the default CGM screen view gives the current numerical estimate and 36 previous glucose values (shown as a trend graph) over the past 3 hours. In routine use, screen views occur an average of 29 ± 18 times per day.[6] The availability of comprehensive glucose data allows CGM users to base management decisions on patterns, rather than just the current point estimate of glucose concentration. Rate of change (ROC) arrows provided on the CGM display may have a greater impact than the glucose value on the need to dose insulin and in determining insulin dose amount,[7] and specific recommendations for basing treatment decisions on these ROC arrows have been published.[8]

Even when CGM data were limited to adjunctive-only use, off-label use was common: in one survey, half of the CGM users indicated that they would treat a nighttime low glucose alert without a confirmatory fingerstick, and 34% indicated that they would dose insulin for hyperglycemia without SMBG confirmation.[7] A separate survey[9] revealed that 69% of Dexcom CGM users regularly use CGM alone to adjust bolus insulin doses. None of these patients had the advantage of training on when, how, or when not to use CGM for dosing decisions due to the lack of a labeled indication.

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Given the quantity and manner in which CGM data are presented, the premise that any particular CGM reading could form the basis of a treatment decision may not be fully justified. CGM data are interpreted in context and CGM users, whether they use the data adjunctively or nonadjunctively, also have the benefit of alerts which mitigate risks from transient inaccurate values. Further, CGM requires daily calibrations; each calibration can provide a user with reassurance or result in a potentially reportable complaint.

Third and most important, there is a mismatch between the question posed and the anecdotes reported. The question of whether requiring fingersticks impacts safety among CGM users were resolved by the REPLACE-BG study, results of which were recently published.[10] Because the REPLACE-BG results may not be generalizable to youth, or to individuals with hypoglycemia unawareness, further studies are needed; however, simulations presented at the FDA advisory board meeting[11] suggest that hypoglycemia-unaware individuals may particularly benefit from using the comprehensive CGM data.

CGM for Insulin Dosing

There are three main approaches to glucose monitoring to guide insulin dosing and diabetes management decisions. First, the decisions may be entirely based on fingerstick values. The low frequency of SMBG testing reported in the T1D Exchange Clinic Registry[12] and resultant long between-test intervals limit the value of this approach. Problematic hypoglycemia and sustained hyperglycemia remain common in insulin users and data from many outcome studies[13] and registries[14] suggest that getting more people using CGM will improve glycemic control. The second approach in which CGM data are used as an adjunct to fingersticks maintains the requirement for frequent, painful, and burdensome blood glucose testing.[15] This requirement likely contributes to the current, low penetration rate of CGM. The third approach—the option to use CGM data nonadjunctively—reflects current use and offers several benefits. I anticipate a reduction in the burden of fingerstick testing, increased adoption and persistent use of the technology, and development of training materials to discuss when and how best to use CGM.

While the author presented interesting data and interpretations, and we agree that the nonadjunctive use of Dexcom CGM is not without risk, I disagree with the recommendation for redundant glucose measurements and maintenance of the status quo requiring fingersticks for all diabetes management decisions. I believe this approach is overly conservative, and fails to account for the current realities around CGM use.

Abbreviations

CGM, continuous glucose monitoring; MAUDE, manufacturer and user facility device experience; ROC, rate of change; SG, sensor glucose; SMBG, self-monitored blood glucose.

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