Journal of Diabetes Science and Technology
2017, Vol. 11(4) 856–857

DOI: 10.1177/1932296817704446
journals.sagepub.com/home/dst
SAGE

The Safety of Nonadjunctive Use of Continuous Glucose Monitors for Insulin Dosing: Still Not Resolved

Alan R. Shapiro, MD, MSPH[1]

Keywords
CGM accuracy, continuous glucose monitor, MAUDE, blood glucose meter, self-monitored blood glucose, text mining

In response to my article expressing concern about the potential hazards of relying on continuous glucose monitors (CGM) for dosing insulin without a confirmatory reading,[1] Dr Price wrote a commentary[2] which requires a reply.

Although we both agree that consistently accurate CGMs would be foundational in transforming the management of diabetes, particularly in persons taking insulin, there is a clear difference in our perspectives. Dr Price notes that removing the requirement for confirmation of CGM readings is good because it will "increase adoption and persistent use of the technology." True, but more important is the widespread patient morbidity likely to ensue from unduly relying on a device that is sporadically inaccurate. Furthermore, he notes that the requirement for confirmatory fingersticks "contributes to the current, low penetration rate of CGM." Again, another perspective is that it also helps reduce the morbidity that could otherwise occur from using the device with undue confidence in its accuracy. The data about 25 000+ reports of CGM inaccuracy are summarized as "interesting"; an alternative interpretation is that they are of great concern.

The commentary goes on to assert that the REPLACE-BG study "resolved" the question of whether confirmatory fingersticks are needed for safety. The authors of the REPLACE-BG study were careful to limit the applicability of the results to patients "meeting the eligibility criteria" for the study, specifically persons without hypoglycemic unawareness, no persons with diabetes under the age of 18, and, most importantly, persons with diabetes who have previously demonstrated that they are least susceptible to hypoglycemia. This leaves a very substantial proportion of persons with diabetes for whom the question of safety has not been "resolved." Dr Price also points to simulations presented by Dexcom to the FDA that "suggest that hypoglycemia-unaware individuals may particularly benefit from using the comprehensive CGM data." It should be added, however, that because of certain assumptions in the simulations, the FDA concluded that "the results of the simulations were not helpful in informing safety and effectiveness of the device and these simulations were therefore not considered in the determination of device safety and effectiveness."[3] If CGM data are sufficiently inaccurate, glycemically unaware individuals would be at particular risk.

Dr Price points to potential inaccuracies in self-monitored blood glucose (SMBG) devices as a cause of reported discrepancies. Surely there are some cases where this could be the case, but there are many reports in the MAUDE database in which a Dexcom CGM was showing a value in the 90-120 mg% range, while glucose measurements obtained by the emergency personnel resuscitating a patient showed values below 30 mg%. In such cases, the patient's clinical condition provides the evidence that it was the CGM reading that was inaccurate. Furthermore, Table 1 of my article emphasized that, just as faulty handwashing can lead to erroneous SMBG results, there are many ways in which faulty practices can throw off CGM results as well. Dr Price states that "there are tens of thousands of inaccuracy complaints in the MAUDE database against meters." In fact, since 2015, although blood glucose meters are currently used an order of magnitude more frequently than CGMs, there are more complaints in the MAUDE database about Dexcom CGM inaccuracy than there are about *all* blood glucose meters taken together.

Dr Price correctly decries the many unsubstantiated reports of complaints found in the MAUDE database. But these reports come from the manufacturer. Ideally, they have the opportunity and the responsibility to provide the well-documented, well-considered case reports that could contribute to uncovering the root causes of device inaccuracy. In 146 reports from Dexcom in the MAUDE database, in response to an episode of severe hypoglycemia attributed to CGM inaccuracy, the manufacturer offers as explanation: "It should be noted that diabetes mellitus is a known cause of hypoglycemia." With all its many manifestations, diabetes mellitus is not a cause of hypoglycemia. Instead, hypoglycemia in diabetes is a frequent consequence resulting from current medicine's best, but imprecise, efforts at providing replacement insulin. CGMs exist to help avoid the hypoglycemic episodes that would

[1]Department of Medicine, New York University School of Medicine, New York, NY, USA

Corresponding Author:
Alan R. Shapiro, MD, MSPH, 5 Pheasant Run Rd, Pleasantville, NY 10570, USA.
Email: alan.shapiro@med.nyu.edu

otherwise occur. So when the device fails to prevent these episodes, there should be a more serious effort devoted to investigating the reasons for the inaccuracies.

The issue of nonadjunctive use of CGMs for insulin dosing is still not resolved for persons with diabetes. There have been over 8000 additional complaints to the FDA concerning Dexcom inaccuracy since my article was written. Although there are, of course, many situations in which diabetes management decisions can be made with only a ballpark estimate of blood glucose level and trend, it is risky to assume that the current CGMs are consistently accurate enough to be used nonadjunctively for the precise dosing of insulin. We need to find the causes of the sporadic inaccuracies and fix them.

Abbreviations

CGM, continuous glucose monitor; FDA, Food and Drug Administration; MAUDE, Manufacturer and User Facility Device Experience; SMBG, self-monitored blood glucose.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. Shapiro AR. Nonadjunctive use of continuous glucose monitors for insulin dosing: is it safe? *J Diabetes Sci Technol*. 2017.
2. Price D. Commentary regarding Shapiro, "Nonadjunctive use of continuous glucose monitors for insulin dosing: is it safe?" *J Diabetes Sci Technol*. 2017.
3. US Food and Drug Administration. Dexcom G5 Mobile continuous glucose monitoring system summary of safety and effectiveness data. Premarket approval P120005/S041. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041b.pdf. Accessed January 2, 2017.