



COMMENT ON HÁSKOVÁ ET AL.

Real-time CGM Is Superior to Flash Glucose Monitoring for Glucose Control in Type 1 Diabetes: The CORRIDA Randomized Controlled Trial.

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The Comparison of CGM in Randomized Study of Real-time and Intermittently Scanned Systems in T1D With Normal Awareness of Hypoglycemia (CORRIDA) study (1) has compared real-time continuous glucose monitoring (rtCGM) and intermittently scanned CGM (isCGM) (also termed flash glucose monitoring) in people with type 1 diabetes (T1D) during a 4-day exercise regimen and over 4 weeks at home. CORRIDA concluded that rtCGM is superior to isCGM in reducing the percentage of time below range (%TBR) and increasing the percentage of time in range (%TIR) in adults with T1D and normal hypoglycemia awareness. We must comment on the glucose sensor-derived conclusions reported.

First, all baseline data were collected using the iPro2 rtCGM device (Medtronic), whereas study outcomes used either the Guardian Connect Mobile rtCGM (Medtronic), which like the iPro2 requires twice daily calibration with blood glucose readings, or the FreeStyle Libre isCGM system (Abbott Diabetes Care), which is factory calibrated. Since the precision of blood glucose testing technique affects the accuracy of glucose readings, the sensor-derived data cannot be compared between the study arms. Notably, only the isCGM system is approved for insulin dosing without adjunctive blood glucose tests. Ultimately, three different glucose sensor systems have been used, each with different performance characteristics,

especially at low glucose. Making objective comparisons between the data is not possible. These concerns are common to the Impact on Hypoglycaemia Awareness of Real Time CGM and Intermittent Continuous Glucose Data (IHART-CGM) study cited by the authors, which are acknowledged (2).

The small study size also introduces bias since the isCGM arm is more than 70% female, which may affect the iPro2-recorded baseline data. Although the baseline measures are not significantly different between the study arms, there is a trend for baseline isCGM values for %TBR and %TIR to be lower than for the rtCGM arm, and for the percentage of time above range (%TAR) to be higher. In the exercise phase, gender bias may have influenced the outcomes and possibly the 4-week home phase. Together, these biases prevent objective interpretation of the significant differences for %TIR and %TAR. When comparing change within each study arm, the data show consistent trends between the devices.

Changes in %TBR are problematic since factory-calibrated FreeStyle Libre sensors have different sensitivity and specificity at low glucose compared with rtCGM systems (3). Also, the CORRIDA protocol uses the masked iPro2 for 6 days after randomization to check for bias only in the isCGM arm, which assumes the iPro2 and the Guardian Connect have comparable performance, which is incorrect (4,5). Since baseline

readings for isCGM subjects were taken with the iPro2 device, which has the least accuracy in the 40–80 mg/dL range (5), any changes from baseline cannot be compared. Significant reductions in %TBR shown in the IMPACT study in T1D using isCGM over 6 months were largely achieved after the first month, so the short duration of the CORRIDA study cannot explain the discrepancy. The changes in %TBR are hard to reconcile between the two studies other than the inconsistencies of the protocol using three incompatible sensor systems in CORRIDA. In understanding the comparative efficacy of different glucose sensors, objective studies must accommodate key differences in the calibration, sensitivity, and specificity of each system used for intervention and monitoring. Ultimately, monitoring devices must be consistent throughout the study and across all arms.

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References

1. Hásková A, Radovnická L, Petruželková L, et al. Real-time CGM is superior to flash glucose monitoring for glucose control in type 1 diabetes:

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the CORRIDA randomized controlled trial. *Diabetes Care* 2020;43:2744–2750

2. Oliver N, Reddy M. Reply to Seibold and Schlaeger iHART: methodological inconsistency precludes hypoglycaemia conclusions. *Diabet Med* 2018;35:1619–1620
3. Bailey T, Bode BW, Christiansen MP, Klaff LJ, Alva S. The performance and usability of a factory-calibrated flash glucose monitoring system. *Diabetes Technol Ther* 2015;17:787–794
4. FDA Summary of Safety and Effectiveness Data. Accessed 12 February 2021. Available from https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017b.pdf
5. FDA Summary of Safety and Effectiveness Data. Accessed 12 February 2021. Available from https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150029B.pdf