Analysis of “Performance of a Factory-Calibrated, Real-Time Continuous Glucose Monitoring System in Pediatric Participants With Type I Diabetes”

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Abstract

Accuracy of sensors play an important role in the acceptance and long-term use of CGM which is related to improved glycemic outcome. This has been lower in children and adolescents in the past for reasons such as size of the device, pain, and necessity to calibrate sensors but also inaccuracy and perceived nonreliability on alarms among others. In the study of Welsh et al, performance of a new, factory-calibrated sensor was assessed. The accuracy of the sensor, as measured in MARD, paired values within 20/20% or 15/15% and surveillance error grid analysis showed very good results, although less so in low value range <70 mg/dL, falling rate of change, and on first day of use. Accurate glucose measurements especially in these incidences are of utmost importance to people with diabetes as their treatment decisions are based on these, also in the beginning of sensor use.

Keywords

glucose sensor performance, clinical accuracy, MARD, continuous glucose monitoring, advanced algorithm, factory calibrated

The use of continuous glucose monitoring (CGM) systems changed dramatically the way people with diabetes, caretakers, and diabetes teams look at their glucose values. Since then studies have shown that glycemic control, as measured in A1c, frequency and duration of hypoglycemia, and glycemic variability have improved, especially in adults. In children and adolescents, this could not been shown to that extent, and reasons stated to underlie this include inaccuracy of the sensor and impracticability, among others.^{1,2}

In the study of Welsh and coauthors (in this issue), the performance of a new CGM sensor was assessed as determined by different measurements of accuracy in children and adolescents with T1D. A special feature of the G6 sensor is that it is factory calibrated and therefore does not need calibration by the people with diabetes, which adds tremendously to its practicability. Also, a longer wear time of 10 days, an improved insertion device, and noninterference with acetaminophen, a drug widely used in pediatrics, are further properties of the new device. As the duration of use of CGM devices is directly correlated with improvement of glycemic control, these so-called soft qualities contribute to the success of sensor use.³

The accuracy assessment of the sensor by comparing estimated glucose values (EGV) from sensor data with temporally

matched YSI data as well as trend accuracy assessment by comparing rate of change (RoC) over a wide range of glucose concentration are an established and widely used method. The levels of glucose concentrations used here are clinically relevant, but especially the RoC assessments are of special interest, as the interpretation and use of RoC as depicted as trend arrows on the CGM devices are more and more coming into focus of clinical work.^{4,5}

Accuracy of CGM sensor expressed as MARD is standard, but the expression as the proportion of the paired values within the $\pm 20\%$ or ± 20 mg or even 15/15% is more meaningful for people with diabetes.⁶ Both being well over 90% (20/20% with 96.2% and 15/15% with 91.1%) show a trustworthy accuracy for clinical and day to day use. This is so important because people with diabetes base their treatment decisions on these values at least since the nonadjunctive claim and the CGM systems will also being used more and more as an essential part in closed loop systems. Since

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this sensor also needs some run-in time, the results on day 1 of sensor use are, in all categories, less accurate compared to those of the following days, which can be of great relevance and is somehow disturbing as people with diabetes of course rely on the sensor data on day 1 as well. The same holds true for the comparative inaccuracy in the low range (<70 mg/dL) with values of 92.6% for 20/20% and 81.5 for 15/15% as well as a MARD of 13.3. This is also known for other CGM systems but still annoying for people with diabetes because especially low glucose values are disturbing, cause fear, and often need fast treatment decisions.⁷

A overall MARD of 7.7 confirms these data only but is not so easy to translate into day-to-day relevance. Using the surveillance error grid analysis in this assessment can be of more relevance as it depicts the risk of inappropriate treatment decisions because of an inaccurate measurement. Welsh and coauthors present that nearly 99% of the measurements showed no risk (92%) or a slight lower risk (7.6%). Therefore, the risk for people with diabetes (or closed-loop systems) to make an inappropriate treatment decision based on the measurements with this CGM system is very low.

The assessment of RoC accuracy showed again good results with over 95% in the 20/20% range, except for fast falling values, range <-2 mg/dL/min, with only 81.8% in 20/20%. This is again relevant in a clinical setting as fast falling glucose values compel people with diabetes to action and inaccuracy in RoC might force them to inappropriate treatment decisions. Recommendations on how to react to trend arrows appropriately are being developed, and the results of the treatment adjustments depend naturally also on the accuracy of RoC.

Despite these limitations, a factory-calibrated rtCGM system with the demonstrated accuracy and a wear time of 10 days represents a great step forward in the treatment of diabetes in children and adolescents. The fact that the study was performed and sponsored by the company manufacturing the device can be called a limitation but should not per se contest it. But one should not overlook other reasons for not using CGM in children and adolescents apart from sensor inaccuracy and nuisance alarms from glucose values that are implausible. Size of the sensor and pain during insertion of the sensor, size of the transmitter, as well as so-called “data-overload” because of the continuous glucose monitoring and changes of the RoC are topics that cannot be neglected. People with diabetes, their families, and their caretakers have to be educated and trained to use this information the right way; this would be done best in a structured teaching course and ongoing close consultations, at least in the beginning.⁸ All stakeholder in the field must ensure that this technology is made available and will be reimbursed to all patients in need and with the right indications. Studies with the right and meaningful parameters on glycemic control as well as patient-reported outcomes

(PRO) will be needed for this and are under way, as stated by the authors.

The study of Welsh and coauthors shows in a well-designed and -performed study very good results on accuracy of a new, factory-calibrated sensor that will help children and adolescents with their families to cope with the burden of T1D.

Abbreviations

EGV, estimated glucose value; MARD, mean absolute relative difference; PRO, patient-reported outcomes; RoC, rate of change; rtCGM, real-time continuous glucose monitoring; T1D, type 1 diabetes mellitus.

Declaration of Conflicting Interests

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References

1. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Tamborlane WV, Beck RW, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med*. 2008;359(14):1464-1476.
2. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Beck RW, Buckingham B, et al. Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. *Diabetes Care*. 2009;32(11):1947-1953.
3. Mauras N, Beck R, Xing D, et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. *Diabetes Care*. 2012;35(2):204-210.
4. Klonoff DC, Kerr D. A simplified approach using rate of change arrows to adjust insulin with real-time continuous glucose monitoring. *J Diabetes Sci Technol*. 2017;11(6):1063-1069.
5. Laffel LM, Aleppo G, Buckingham BA, et al. A practical approach to using trend arrows on the Dexcom G5 CGM system to manage children and adolescents with diabetes. *J Endocr Soc*. 2017;1(12):1461-1476.
6. Kirchsteiger H, Heinemann L, Freckmann G, et al. Performance comparison of CGM systems: MARD values are not always a reliable indicator of CGM system accuracy. *J Diabetes Sci Technol*. 2015;9(5):1030-1040.
7. Polonsky WH, Hessler D. Perceived accuracy in continuous glucose monitoring: understanding the impact on patients. *J Diabetes Sci Technol*. 2015;9(2):339-341.
8. Gehr B, Holder M, Kulzer B, et al. SPECTRUM: a training and treatment program for continuous glucose monitoring for all age groups. *J Diabetes Sci Technol*. 2017;11(2):284-289.