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Analysis of "Accuracy of a Seventh-Generation Continuous Glucose Monitoring System in Children and Adolescents With Type 1 Diabetes"

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Abstract

In an article in the *Journal of Diabetes Science and Technology*, Laffell et al examined the accuracy and performance of a seventh-generation "G7" continuous glucose monitor (CGM) system in participants with type 1 diabetes aged 2 to 17 years. The study had notable points which increase the generalizability of the authors' findings to usual clinical practice, such as accuracy assessment across a wide range of glycemia in the arm and abdominal area, at variable rates of change and time periods (beginning and end of sensor wear). However, accuracy measurements in the younger cohort (2-6 years old) were relatively few. Overall and per-sensor accuracy assessments using standard accuracy metrics were consistently high. The authors also highlighted the enhanced features of the G7 system compared to earlier generation systems, which support better usability.

Keywords

real-time continuous glucose monitoring, type 1 diabetes, Dexcom G7, sensor accuracy, children and adolescents

Glucose monitoring is a key foundation in type 1 diabetes management. Advancements in real-time continuous glucose monitors (RT-CGMs) in the past decade have played an important role in diabetes care, from adjuvant use of RT-CGM with multiple daily injections and insulin pump therapy, to automated insulin delivery systems. Studies have shown that RT-CGM use leads to improved clinical and patient-related outcomes.[1,2] Thus, advancements in RT-CGM systems to support the needs of people with type 1 diabetes and their families remain of significant interest. In this issue of *Journal of Diabetes Science and Technology*, Laffell et al performed a study to evaluate the performance of a novel seventh-generation "G7" CGM (Dexcom Inc, San Diego, CA) in children and adolescents (2-17 years old) with type 1 diabetes.[3]

This multicentre single-arm study recruited 132 participants aged 7 to 17 years and 32 participants aged 2 to 6 years. Real-time continuous glucose monitor readings in the older cohort were matched with arterialized venous blood glucose values measured using a YSI analyzer during two to three clinic sessions, whilst RT-CGM readings in the younger cohort were matched with capillary blood glucose values measured using Ascencia CONTOUR® NEXT meters during one clinic session. The latter approach in the younger cohort was to reduce the burden of visits and intervention. The authors used recommended standard metrics for sensor accuracy and performance assessment across a wide range of glycemia which increases the clinical relevance and allows comparability to other studies. A relatively large number of matched pairs (>15,000) analyzed in the overall group were in the reportable range (40-400 mg/dL). The experiment had other notable points that increase its generalizability to usual clinical practice, such as accuracy assessments at various anatomical sites, rate of change, and time periods (beginning and end of sensor wear).

Across the younger and older cohorts, overall and per-sensor mean absolute relative difference (MARD) were consistently high with objectively good findings based on the %15/15, %20/20, and %30/30 agreement rates. In the hypoglycemic range (40-60 mg/dL, >400 matched pairs), sensor accuracy was relatively higher in the arm than in the abdomen (%20/20; 85.3 vs. 73.1%), which may influence selection of appropriate sensor sites by patients and health-care professionals. Both sites however performed equally well in

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the euglycemic range, with relatively higher sensor accuracy in the hyperglycemic range. Accuracy in hypo- and hyperglycemia range is important to inform treatment decisions. Compared to its predecessor, the G7 RT-CGM system has a shorter warm-up time (30 min vs. 120 min), allowing sensor readings to be available and can be used earlier for decision-making. It is assuring that day-1 MARD in both arm and abdominal sites were comparable and improved with longer periods of sensor wear (MARD of 7.3% at day 10.5). Although lower sensor accuracy on day-1 is commonly observed across various RT-CGM devices, there has been much improvement over the past years.[4] Compared to capillary blood glucose, sensor accuracy in the younger children (2-6 years old) showed a ±20/20% agreement rate of 92%, which is well within the U.S. Food and Drug Administration (FDA) special controls necessary for clearance as an iCGM device.[5] Taken together with the strong MARD data in this age group, the accuracy of G7 RT-CGM may help mitigate fear of hypoglycemia commonly observed in parents and caregivers of this population, supporting better quality of life.

The authors are to be commended for performing this study in a cohort where technology arguably has a significant role to play in type 1 diabetes daily management, but which remains understudied compared to their adult counterparts. The improved sensor accuracy outcome of G7 RT-CGM in this study, compared to its predecessors, is an important technological step which no doubt many will be looking forward to. However, another important aspect which this study highlights is the enhanced features supporting better usability. It is widely known that glycemic outcomes are closely related to sensor usability rates. Unfortunately, sensor use attrition has been reported to be higher among younger age groups, compared to older adults.[6,7] The positive aspects of the G7 design and usability as reported by the authors include a smaller, discrete, and slimmer profile, an integrated all-in-one unit (no separate transmitter) and less-painful insertion. Alarm burden, another limiting factor in sensor usability, may be mitigated by the unique customizable alarm features of the G7 system (delayed high and temporary suspend of alarms). The longer-term impact of these new features on user experience and outcomes should be assessed in future studies.

The relatively restricted number of matched pairs (343 vs. 15,809) and glycemia range in the very young age group could be construed as a limitation of the study, albeit understandable given the practical challenges. The prevalence of skin irritation to adhesives was reported to be low in this study, and the authors cited that this may be due to the lower area of contact between the adhesive patch and skin. In other studies, up to 60% of those using sensors or pumps reported skin reactions to device adhesives, leading to interruption or discontinuation of device use.[8,9] As these findings are commonly associated with long-term use, longer-term studies would be helpful to confirm the authors' findings.

As automated insulin delivery systems become more widely used in this age group, novel and accurate RT-CGM systems will be a necessity for effectiveness and safety. Although not the scope of this current paper, future work should evaluate the impact of socioeconomic factors, such as income and ethnicity, on accessibility to novel RT-CGM systems. It is the hope that the persistent socioeconomic disparities which still exist in 2022, will eventually abate in the future and allow those who would benefit from technological advancements in diabetes, avail of it irrespective of their background.

Abbreviations

MARD, mean absolute relative difference; RT-CGM, real-time continuous glucose monitor.

Declaration of Conflicting Interests

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