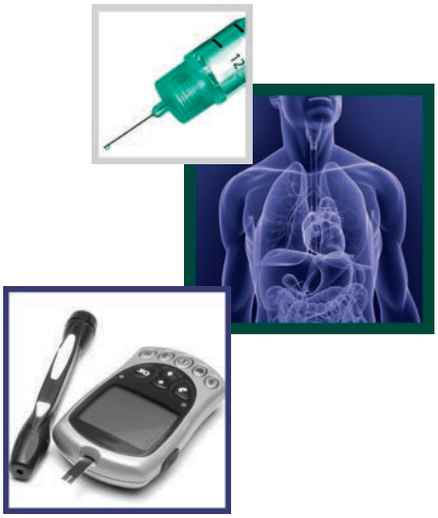
EDITORIAL

What is the role of sensor-augmented pump therapy in young children with Type 1 diabetes?



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"...when using continuous glucose monitoring in the pediatric population, different strategies and greater support may be required, especially as continuous glucose monitoring is essentially a behavior-modification tool."

Over the last 10 years, children with Type 1 diabetes, their families and their healthcare providers have embraced technology in the form of insulin pump therapy. Patient and family satisfaction with pump therapy is high and discontinuation rates are generally low [1]. By contrast, the pediatric community has not responded as positively to real-time continuous glucose monitoring (CGM), even though it uses similar technology, namely, a subcutaneous catheter, changed at home by the user every 3–7 days, and an external 'pager-size' device or the pump itself with which the glucose sensor communicates. Several large randomized controlled trials have conclusively demonstrated a reduction in mean A1c in adult CGM users, but not in youths or children [2–4]. Given the results of these studies, what is the role for CGM in young children, especially in those using pump therapy (i.e., sensor-augmented pump therapy)?

Systematic reviews have shown that in children, standard pump therapy with self-blood glucose monitoring (SBGM) leads, at best, to a modest improvement in A1c compared with multiple daily injections (MDI), but at twice the cost [5]. In the first months after pump initiation, when children and their parents are willing to perform SBGM six to ten times per day, including overnight, A1c improves significantly, but thereafter in many children, frequency of SBGM returns to prepump levels as does their A1c [6].

There are multiple reasons for this commonly observed deterioration in control in children on pump therapy, including missed boluses and decreased parental involvement [7,8]. However, the requirement for frequent SBGM for pump adjustments and day-to-day operation of the pump is a significant contributor to the rise in A1c. The insulin pump is a precision instrument designed to match insulin delivery to the child's specific and changing needs throughout the day and night. However, the input provided to it through SBGM is inadequate to enable optimal pump functioning, especially given the human and behavioral factors affecting day-to-day glucose variability in children. CGM offers the promise of sufficiently accurate glucose trends and real-time readings to enable children to realize the full potential of insulin pump therapy, beyond the pump honeymoon period. What is the evidence that CGM can deliver on this promise in children?

"Continuous glucose monitoring offers the promise of sufficiently accurate glucose trends and real-time readings to enable children to realize the full potential of insulin pump therapy..."

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First, children who use CGM for 6 or more days per week have a greater reduction in A1c compared with those using SBGM [2,3]. Furthermore, children who use CGM with MDI or in sensor-augmented pump therapy, are much more likely to achieve and maintain A1cs within their target range (with reduced hypoglycemia) [2,3,9]. One study recently questioned this finding in their trial of CGM in young children, reporting neither an effect on A1c nor an association between frequency of CGM use and change in A1c [4]. This was surprising, as it had been thought that CGM would have a greater benefit in this age group given that parents are primarily responsible for the child's diabetes management. A significant limitation of this study, however, is that glucose levels were set too high in both groups, limiting the potential for change in A1c with any intervention. In addition, the authors acknowledged that there was probably limited use of CGM data by parents in the day-to-day management of diabetes, even though parents reported high satisfaction with CGM.

Second, CGM has the potential to reduce both hyper- and hypo-glycemia, which have been shown to have short-term negative effects on learning and behavior in young children [10,11]. Children who regularly wear CGM spend more time in their target blood glucose range compared with those using SBGM [2,3,12]. These metabolic outcomes are clearly important and desirable, especially for young children.

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Third, regular use of CGM may decrease the frequency of nocturnal hypoglycemia, which would be especially beneficial in a young child unable to respond to hypoglycemia independently. Parents of children with diabetes have tremendous fear of hypoglycemia [13]. This fear keeps them awake at night, and leads many parents to get up to check their child's blood glucose every single night, years after the onset of diabetes [14]. The sensor alarms, annoying as they can be, signal to the user (or the parent) that hypoglycemia is occurring so corrective action can be taken. Unfortunately, many families report that they sleep through CGM alarms, or turn them off owing to frustration. This experience has taught us to activate alarms selectively and to encourage and support retrospective examination of CGM data, with regular computer uploads, to enable families to adjust overnight basal rates and prevent future hypoglycemia. Early studies of the low glucose suspend (LGS) feature of Medtronic's Veo™ pump suggest that it can significantly decrease nocturnal hypoglycemia in those at highest risk [15]. Furthermore, adults who use LGS report feeling more secure at night [15]. With or without LGS, parents tell us that CGM enables them to sleep through the night more often, knowing that something else (CGM) is helping to watch over their child's safety.

Finally, regular CGM use, especially in pump users, enables the pump to be used more effectively to match the insulin delivery to the child's variable and often rapidly changing needs. When pump therapy utilizes only the incomplete information provided by SBGM, its potential is limited, so it is not surprising that effectiveness of standard pump therapy decreases over time, particularly as frequency of SBGM wanes, averaging four to six times per day in most pediatric pump users. CGM fills in the gaps between SBGM checks, with up to 12 glucose readings per hour, allowing glucose trends to be observed and acted upon in real time, to fine-tune pump therapy.

It is important to point out that the age-related differences in CGM outcomes that have been observed in various studies are not related to differences in CGM efficacy (i.e., whether CGM works when used the way it is intended), but instead, to differences in the frequency of CGM use (adherence) [16]. Simply put, CGM only works if you wear it, and the more often you wear it, the better it works. The children and adolescents who participated in these CGM studies have not been willing to wear CGM as often as their adult counterparts. The main message from these studies is not that CGM does not work in the pediatric population, but that these children and adolescents have been less willing to wear CGM compared with adults. Many families do not perform SBGM at the recommended frequency [6] or use the SBGM results adequately in the day-to-day management of their child's diabetes, yet we do not discount the benefits of consistent and frequent blood glucose monitoring. Rather, we focus on education, support and motivational strategies to encourage families to use a tool that we know is effective when used as directed. Similarly, when using CGM in the pediatric population, different strategies and greater support may be required, especially as CGM is essentially a behavior-modification tool. For example, the timing of CGM initiation may be a more significant factor in its successful use with children. The high CGM adherence

observed amongst the children and youth using sensor-augmented pump therapy in the STAR 3 trial, suggests that the pediatric population may be more receptive to the introduction of CGM at the time of pump initiation, as compared with adding CGM to the regimen of an established pump or MDI user. Our group is currently evaluating this strategy in the CGM TIME Trial [101].

Significant challenges and barriers to the effective use of CGM remain, even though real-time CGM has been available for 6 years, with third and fourth generation models now available. These barriers include discomfort with the sensor's insertion and wear, inaccurate readings (although most are due to improper calibration or failure to appreciate the lag time effect), the nuisance of alarms (particularly when they are false), the cost of CGM and difficulty obtaining third party coverage for CGM supplies [17]. Addition of CGM to an adolescents' already intensive diabetes regimen (pump or MDI) may have negative psychological consequences related to anxiety and the perceived extra burden [18]. These challenges are real and a significant impediment to CGM use for some children and their parents.

However, there is clearly substantial benefit for the children and families who continue to use CGM on a regular basis, especially in sensor-augmented pump users. For them, the advantages of CGM clearly outweigh the disadvantages, and the result is better health outcomes for these children. The current generation of CGM devices is not perfect, but just like the first home blood glucose meters, the technology is good enough to help children with diabetes now. More research is needed, however, regarding how best to introduce and support ongoing CGM use in the pediatric population so that young children can achieve the same benefits from CGM as adults.

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■ Website

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