Utilizing Hybrid Closed-Loop Technology for T1D Pediatric Patients

Announcer Introduction:

You're listening to to *Diabetes Discourse* on ReachMD. Joining us to talk about his study, titled Trial of Hybrid Closed-Loop Control in Young Children with Type 1 Diabetes, which was published in *The New England Journal of Medicine* in 2023 is Dr. Paul Wadwa. He's a Professor of Pediatrics and the Medical Director of the Pediatric Clinic at the Barbara Davis Center for Diabetes at University of Colorado Anschutz Medical Campus. Let's hear from him now.

Dr. Wadwa:

The control of type 1 diabetes in young kids tends to be a little more difficult than older kids or in adults because in very young kids their activity level or their diet—what they're eating—may be less predictable, and so we tend to see more variability in their blood sugars, and the management of their diabetes and their safety can be more challenging for families. So the objective of this study was to look at a hybrid closed-loop system, which includes Control-IQ technology, which is software developed at the University of Virginia and to evaluate the safety and efficacy in kids age two to less than six years old with type 1 diabetes. And this is really important because use of hybrid closed-loop systems, they greatly increase the level of blood sugar control in this age group but also add an element of safety that previously wasn't available prior to this technology being available.

The methods for this study included recruitment of 102 children age two to less than six years old at three different clinical sites, and that includes our site at the Barbara Davis Center at the University of Colorado Anschutz Medical Campus, the site at Stanford University, and the site at University of Virginia. And when we recruited those participants, they were then randomized two-to-one using a hybrid closed-loop system versus their standard care. A majority of the patients enrolled in the study were using insulin prior to the study, but there was a subgroup that were using injections, and those that were in the control group who were on injections stayed on injections during that time, and then everybody used continuous glucose monitoring. They used Dexcom G6 continuous glucose monitors during the study. And then once they get randomized, we follow them for 13 weeks, and the primary outcome there was to look at time in target range or the time that they had glucose levels by sensor in the 70 to 180 milligrams per deciliter range. Secondary outcomes included time over 250 milligrams per deciliter, and then time less than 70 milligrams per deciliter, and then time less than 54 milligrams per deciliter. We also evaluated safety and used incidence of severe hypoglycemia and incidence of diabetic ketoacidosis to evaluate for safety.

What we found in this study was that the time in target range increased significantly in the participants using hybrid closed-loop technology and was much higher than the group that was on standard care, specifically, those in the hybrid closed loop at baseline had time in target range of 56.7 percent and that increased during the 13 weeks to 69.3 percent; the control group similarly started at 54.9 percent, and then it only changed to 55.9 percent; so we really saw a significant increase. If you look at the difference between the two groups, the difference was about 12 percent, and that would be about three hours per day more in target range, which was really quite striking.

The secondary outcomes included time over 250, and the group on hybrid closed loop had significantly less time over 250 than the standard care group. And fortunately, both groups had a relatively low amount of hypoglycemia or time less than 70 milligrams per deciliter and time less than 54 milligrams per deciliter, and that remained low throughout the study. So those were the key outcomes.

In terms of safety, there were very few events. There were three events of severe hypoglycemia and one of DKA, and those episodes were not significantly different between the two groups, so that tells us that we found a significant improvement in glycemic control using this hybrid closed-loop system compared to standard of care with no changes in safety and found that the system was safe to use in this young group, which is really new information that we did not have before.

I would like to mention that there was one other key component and that is that this study was conducted in 2021 and 2022 when virtual trainings and virtual care were really increasing quite a bit. What we found was that we offered virtual training for the participants in the study, and a vast majority used virtual training instead of in-person visits and did just as well as those participants doing in-person visits, so we did learn that the virtual training was safe and effective as well. And that was a key component of the study also.

We feel like quality of life improved really for the parents or caregivers or family members of young children with type 1 diabetes. Certainly, caring for a child who's on insulin and dependent on that insulin at this very young age can be quite stressful, and the quality of life measures that were done during the study show that parents or caregivers reported improved sleep, decreased stress and concern, and overall were very happy with how the system tended to change their quality of life and saw an improvement for the family as a whole. The ability to detect low blood sugars or have less low blood sugars at night was really a key component of that.

In terms of the context of this study, we collected data in 2021 and 2022, and then the findings were published in 2023, so we're a little ways out from when we completed this study. And the technology has really continued to evolve, and so what we showed with this system was that this particular system was safe and effective in kids in this age range. And at that time there were really limited options for children at this age. There are now several different options for hybrid closed-loop systems that can be used in this age range. This is now one of two FDA-approved systems in this age group, and there are other systems available for older kids as well.

So what we take away from this is hybrid closed loop in general is a good option for children with type 1 diabetes, and we try to custom fit which system might be best for that particular child or that particular family so that they can get the best success possible, both in terms of glucose control, time in range safety but also quality of life. We want to use the system that will fit for them and give them the best possible outcomes and also quality of life.

Announcer Close:
That was Dr. Paul Wadwa discussing his recent research on pediatric patients with type 1 diabetes. To access this and other episodes in our series, visit *Diabetes Discourse* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!