Next Generation Automatic Insulin Delivery System Improves Glycemic Control in People with Type 1 Diabetes

Results of NIDDK’s, Fuzzy Logic Automated Insulin Regulation (FLAIR) study showed increased time in range and improved A1C levels in adolescents and young adults who used system

CHICAGO (June 12, 2020) — Medtronic’s Advanced Hybrid Closed-Loop system use in adolescents and young adults with type 1 diabetes (T1D) can lead to improved daytime blood sugar control without an increase in hypoglycemia, according to research presented today at the American Diabetes Association’s® (ADA’s) 80th Scientific Sessions. The presentation, “FLAIR—An NIDDK-Sponsored International, Multi-site Randomized Crossover Trial of AHCL vs. 670G,” shared results of this first comparison of a next generation automatic insulin delivery (AID) system to a currently approved system.

Youth with T1D often have a difficult time achieving optimal blood sugar control, which is important in reducing the risk for diabetes complications. Despite the use of multiple daily injections or insulin pumps and continuous glucose monitoring (CGM), there is still a need for many individuals with T1D to further improve glycemic control without adding to the daily burden of living with diabetes. The utilization of AID systems—sometimes referred to as artificial pancreas—is rapidly becoming a standard of care in the management of T1D. The FLAIR study is the first to compare the efficacy and safety of a next generation AID system, the new Advanced Hybrid Closed-Loop (AHCL) made by Medtronic, to one of two currently approved AID systems in the U.S., Medtronic’s 670G Hybrid Closed-Loop (HCL).

FLAIR enrolled 113 patients with T1D at seven international diabetes centers. The participants, adolescents and young adults, age 14 to 29, used each AID system for three months in a randomized crossover trial. Participants and their diabetes care partners received standardized pump training, including how to account for meals and exercise. Researchers compared how effective each system was at preventing high blood glucose levels during the day (currently the biggest challenge for AID systems) and evaluated how participants adjusted to the daily use of the technology.

Results showed:
- The percentage of time in range (TIR) over 24 hours (meaning blood sugar levels from 70-180 mg/dL) was superior with AHCL vs. HCL. TIR went from 57% at baseline to 67% (AHCL) and 63% (HCL).
- The number of individuals achieving the international TIR consensus target of > 70% TIR went up nearly three fold from baseline when using AHCL compared to increasing almost two fold when using HCL.
- Baseline average A1C levels were 7.9% and A1C decreased to 7.4% with AHCL vs. 7.6% with HCL.
- Both systems were safe when evaluating events of level 3 hypoglycemia or diabetic ketoacidosis (DKA).
- Responses to a user satisfaction survey showed patients preferred the AHCL over the HCL system.
“This age group has traditionally been the most difficult group in which to optimize glucose management and the FLAIR study shows that individuals using any type of therapy, even insulin injections without a pump or CGM system, can benefit from the next generation AHCL AID therapy,” said Richard Bergenstal, MD, co-primary investigator of FLAIR, executive director of the International Diabetes Center at HealthPartners, and past ADA President of Medicine & Science. “There is much interest in the future of advanced technology to treat type 1 diabetes and the AHCL system is a significant step forward for adolescents or young adults who have a hard time managing their glucose levels.”

Research presentation details:

- Dr. Bergenstal will present the results of FLAIR—An NIDDK-Sponsored International, Multi-site Randomized Crossover Trial of AHCL vs. 670G at 2:30 p.m. CT during the symposium listed below.
- Symposium title: The Next Generation of Automated Insulin Delivery Systems for Persons with Type 1 Diabetes—Four New Clinical Trials
- Date: Friday, June 12, 2:00 – 4:00 p.m. CT (all sessions will be recorded and available for viewing for up to 90 days)

For more information, or to schedule an interview with Dr. Bergenstal, please contact Daisy Diaz by phone at (703) 253-4807 or by email at SciSessionsPress@diabetes.org.

About the ADA’s Scientific Sessions
The ADA’s 80th Scientific Sessions, the world’s largest scientific meeting focused on diabetes research, prevention and care, will be held virtually June 12-16, 2020. Leading physicians, scientists and health care professionals from around the world will unveil cutting-edge research, treatment recommendations and advances toward a cure for diabetes. Though the conference will be remote this year, attendees will receive exclusive access to nearly 2,000 original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Learn more and register at scientificsessions.diabetes.org and join the Scientific Sessions conversation on social media using #ADA2020 and #ADAGoesVirtual.

About the American Diabetes Association
Every day more than 4,000 people are newly diagnosed with diabetes in America. More than 122 million Americans have diabetes or prediabetes and are striving to manage their lives while living with the disease. The American Diabetes Association (ADA) is the nation’s leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For nearly 80 years the ADA has been driving discovery and research to treat, manage and prevent diabetes, while working relentlessly for a cure. We help people with diabetes thrive by fighting for their rights and developing programs, advocacy and education designed to improve their quality of life. Diabetes has brought us together. What we do next will make us Connected for Life. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook (American Diabetes Association), Twitter (@AmDiabetesAssn) and Instagram (@AmDiabetesAssn).

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