Medtronic News

STAR 3 Trial Results Confirm Medtronic's Sensor-Augmented Insulin Pump Therapy Achieves Better Glucose Control Than Daily Insulin Injections in People with Diabetes

Results of Study Published in NEJM and Presented at ADA Could Redefine the Standard of Care for People with Type 1 Diabetes

MINNEAPOLIS, Jun 29, 2010 (BUSINESS WIRE) --

In the longest and largest randomized, controlled study of sensor-augmented insulin pump therapy in type 1 diabetes, adult and pediatric patients using the Medtronic MiniMed Paradigm(R) REAL-Time System achieved better glucose control without an increase in hypoglycemia compared to multiple daily insulin injections (MDI), the most common approach to care today. The data also showed a statistically significant reduction in glycated hemoglobin (A1c) levels, which was sustained over a prolonged one-year period for patients enrolled in the sensor-augmented insulin pump therapy arm of the trial. Study results were simultaneously published online in *The New England Journal of Medicine* (NEJM) and presented at a late-breaking clinical study symposium at the American Diabetes Association (ADA) 70th Scientific Sessions in Orlando.

The Sensor-Augmented Pump Therapy for A1C Reduction (STAR 3) trial showed patients (adults, teens and children) on sensor-augmented insulin pump therapy demonstrated a reduction in mean A1C levels that was four times greater than the multiple daily injection group (0.8 percent study vs. 0.2 percent control ($p<.001$). The mean A1C decrease was from a baseline of 8.3 percent to 7.5 percent in the sensor-augmented pump therapy group, compared to only 8.3 percent to 8.1 percent in the MDI group. In addition, for the adult participants in the sensor-augmented insulin pump therapy arm, there was a full one percent reduction in their A1C levels. The study was sponsored by Medtronic (NYSE: MDT) and conducted at 30 sites in the United States and Canada with participation from 485 patients, ranging in age from seven to 70 years (329 adult and 156 pediatric subjects).

"Sensor-augmented insulin pump therapy is a major advancement in the treatment of many people across the age spectrum with type 1 diabetes," said Richard M. Bergenstal, M.D., executive director of the International Diabetes Center at Park Nicollet Health Services in Minneapolis and Clinical Professor for the Department of Medicine at the University of Minnesota. "This data is very important because it provides strong evidence that sensor-augmented insulin pump therapy results in good glucose control with minimal hypoglycemia."

Diabetes association guidelines recommend that most people with diabetes maintain A1C levels of seven percent or below in order to live healthier and more productive lives. Every percentage point drop in A1c blood test results (e.g., from 8.0 percent to 7.0 percent) can reduce the risk of microvascular complications (eye, kidney, and nerve diseases) by 40 percent. The significant decrease in A1C observed in STAR 3 occurred without an increase in the rate of hypoglycemia, which is the most prevalent clinical risk with intensive insulin management. The benefit of the sensor-augmented insulin pump therapy was gained early (i.e., at three months) and sustained during the course of one year. Importantly, the results demonstrated a strong link between increased sensor use and increased benefit. Patients who used the sensor with the insulin pump more than 81 percent of the time reduced their A1C levels by 1.2 percent.

STAR 3 is the first study that confirms sensor-augmented insulin pump therapy provides superior glucose control for children and adolescents, an age group that is particularly challenging to treat due to the social and physiological changes due to growth and maturation. In STAR 3, nearly 44 percent of pediatric patients using sensor-augmented insulin pump therapy achieved the American Diabetes Association's age-specific glucose control targets, compared to only 20 percent of patients in the multiple daily injection group.

"STAR 3 redefines what should be the standard of care for diabetes management. For the first time, with the sensor-augmented insulin pump, adults, children and teens had a sustained improvement in A1C levels, which can greatly reduce the risk of complications from diabetes," said Francine Kaufman, M.D., vice president of global medical affairs of the Diabetes Business at Medtronic. "Furthermore, this study clinically validates our sensor-augmented pump system, the foundation upon which we are building a closed loop system or artificial pancreas. Following on the landmark STAR 3 results, Medtronic will continue to partner with investigators from the best institutions around the world to build a clinical body of evidence that guides diabetes therapy."

About Diabetes

According to the Centers for Disease Control and Prevention, diabetes affects nearly 24 million Americans; of that, nearly one-quarter, or six million people, do not know they have the disease. Diabetes is the sixth leading cause of death in the United States and costs approximately $174 billion per year in direct and indirect medical expenses.

About The MiniMed Paradigm(R) REAL-Time Revel(TM) System

The MiniMed Paradigm(R) REAL-Time Revel(TM) System is the latest generation of Medtronic's sensor-augmented insulin pump therapy. The MiniMed Paradigm Revel System is comprised of three key components: a "smart" insulin pump, a continuous glucose monitoring system and therapy management software. The system incorporates new innovative CGM features including predictive alerts that can give early warning to people with diabetes so they can take action to prevent dangerous high or low glucose events. Information on how to purchase the MiniMed Paradigm REAL-Time Revel System is available at www.medtronicdiabetes.com or by calling 1-800-646-4633.

About the Diabetes Business at Medtronic

The Diabetes business at Medtronic (www.medtronicdiabetes.com) is the world leader in advanced diabetes management solutions, including integrated diabetes management systems, insulin pump therapy, continuous glucose monitoring systems and therapy management software, as well as world-class, 24/7 expert consumer and professional service and support.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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https://news.medtronic.com/2010-06-29-STAR-3-Trial-Results-Confirm-Medtronics-Sensor-Augmented-Insulin-Pump-Therapy-Achieves-Better-Glucose-Control-Than-Daily-Insulin-Injections-in-People-with-Diabetes