Medtronic News

Recent Studies Suggest Benefits of Continuous Glucose Monitoring

On World Diabetes Day, Medtronic Highlights the Growing Clinical Evidence for the Benefits of Continuous Glucose Monitoring in Diabetes Control

MINNEAPOLIS--(BUSINESS WIRE)--Nov. 13, 2009-- In acknowledgement of this year's World Diabetes Day, which calls on all those responsible for diabetes care to understand diabetes and take control, Medtronic, Inc. (NYSE: MDT) highlights the growing body of clinical evidence for Personal Continuous Glucose Monitoring (CGM) in improving glucose control for diabetes patients.

Recent studies continue to suggest that the more often patients use Personal CGM, the greater average glucose control (A1C) they can achieve without increasing hypoglycemia (low blood sugar). Moreover, evidence is mounting for a variety of patients, including those with A1C levels above and below 7 percent, patients moving directly from multiple daily injections (MDI) to Personal CGM, and children using Personal CGM at the onset of their diagnosis. Personal CGM is approved for use by people ages 7 and older in the U.S. and for people of all ages in Canada. Medtronic offers separate Personal CGM devices for U.S. pediatric and adult patients.

"It's very exciting to see the evidence unfold for Personal CGM," said Francine Kaufman, M.D., chief medical officer and vice president, global medical, clinical and health affairs at Medtronic Diabetes. "World Diabetes Day reminds us to acknowledge favorable evidence and incorporate tools into daily practice to improve patients' lives."

Personal CGM reveals fluctuations in glucose levels that often go unnoticed when only standard fingerstick measurements are used. By viewing continuous data and trend graphs, patients can react to high or low glucose levels before they become dangerous. Additionally, this information can help provide insights into the underlying causes of glucose fluctuations, allowing for therapy adjustments to be made to help improve patients' overall health and quality of life.

Six key studies suggesting the benefits of Personal CGM are described below:

GuardControl Trial1 (162 patients, Ages 8-59): The purpose of this study was to understand whether poorly-controlled type 1 patients (A1C levels ≥8.1 percent) previously treated with intensive insulin therapy (insulin pump therapy or MDI) could improve glucose control using Personal CGM. The study revealed a >1 percent A1C reduction in half the subjects and ≥2 percent in 26 percent of the subjects after three months of near daily Personal CGM use.

STAR 1 Trial2 (146 Patients, Ages 12-72): This trial evaluated the safety and efficacy of an insulin pump with Personal CGM compared to an insulin pump alone in subjects with type 1 diabetes already using insulin pump therapy. It is the most prolific glucose sensor accuracy study ever published with more than 60,000 paired data points. The data provide evidence that increased glucose sensor usage enhanced the probability of A1C reduction.

JDRF-Funded Studies 3-5 These landmark studies combine to provide the largest body of Personal CGM data in children, adolescents, and adults. The largest of these studies examined 322 patients (ages 8-72) with poor glycemic control (A1C levels 7 percent to 10 percent). Results at six months3 showed that the use of glucose sensors varied between the age groups, with the most significant results occurring in adults who used Personal CGM regularly. At 12 months,4 nearly 90 percent of these Personal CGM users continued using the therapy and

A1C reductions were sustained despite less intensive follow-up. Study results5 of patients with good glycemic control (A1C levels <7 percent), demonstrated improved glucose control with less hypoglycemia when using Personal CGM.

REAL Trend Study6 (132 patients, Ages 2-65): This study investigated whether subjects using MDI could benefit from Personal CGM at insulin pump initiation. Results showed that insulin pumps (both conventional and with Personal CGM) result in significant A1C improvement compared to MDI therapy. The greatest A1C reduction occurred when using Personal CGM more than 70 percent of the time. Study subjects using Personal CGM achieved nearly a full percentage point in A1C reduction without increasing hypoglycemia.

EURYTHMICS Study7 (83 patients, Ages 18-65): This study demonstrated the additional benefits of moving type 1 patients with poor glycemic control (A1C levels ≥8.2 percent) from MDI directly to an insulin pump with Personal CGM. The Personal CGM group experienced an A1C reduction >1 percent and more than one-third of these patients achieved A1C levels of 7 percent or less without increasing hypoglycemia. No patients in the MDI group achieved this goal.

ONSET Trial8 (160 patients, Ages 1-16): This trial explored whether children newly diagnosed with diabetes can benefit from using an insulin pump with Personal CGM at the onset of their disease. Twelve month data presented orally at the 2009 International Diabetes Federation found that insulin pump therapy at diabetes onset results in lower A1C values compared to historical controls (using insulin injections during the first 12 months after diagnosis). Children using Personal CGM at least once a week experienced significantly lower A1C values, fewer episodes of severe hypoglycemia, and had significantly less C-peptide loss.

Personal CGM Therapies
Medtronic's Personal CGM therapies that integrate insulin pump therapy include MiniMed Paradigm® (522 and 722) insulin pumps. The company's stand-alone Personal CGM therapies include the Guardian® RT System and the Guardian® REAL-Time System.

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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Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 24, 2009. Actual results may differ materially from anticipated results.

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