Medtronic News

New Data Shows Benefits of Medtronic Insulin Pumps for People with Type 2 Diabetes

Study Shows Insulin Pumps Safely Provided Significant, Sustainable and Reproducible Improvements in Glucose Control in Comparison to Multiple Daily Injections

DUBLIN - April 13, 2016 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the publication of new data in *Diabetes, Obesity and Metabolism* from the continuation phase of the OpT2mise study, providing further clinical evidence in support of insulin pumps for people with insulin-requiring type 2 diabetes. The OpT2mise study is the largest randomized controlled trial to compare the efficacy and safety of insulin pump therapy versus multiple daily injections (MDI) for poorly controlled type 2 patients.

Study findings showed that MiniMed® insulin pumps safely provided significant, sustainable and reproducible improvements in glucose control in comparison to MDI. At 12 months, the group that crossed over to MiniMed insulin pumps after an initial six months of MDI doubled their A1C reduction (a blood measurement used to indicate glucose control) from 0.4% to 0.8% while using 19% less insulin.

"The continuation phase of OpT2mise builds on the findings of the initial study period, which showed that insulin pumps helped participants with insulin-requiring type 2 diabetes safely achieve better glucose control, with lower insulin doses, than MDI," said Ronnie Aronson MD, FRCPC, FACE, lead author of the continuation phase of the study and executive director at LMC Diabetes & Endocrinology in Toronto, Ontario, Canada. "We found that participants who switched from MDI to insulin pumps were able to achieve these same results by the 12-month mark. Given that many patients with type 2 diabetes have difficulty achieving glycemic control, these additional data demonstrate that insulin pumps provide a significant advantage over MDI with a safe and consistent effect."

For people with diabetes, glucose control is key to preventing both short-term and long-term complications. A 1% reduction in A1C is associated with a reduction in the risk of long-term complications like stroke, heart disease, eye damage and kidney disease reduces by 40%. 1,2

Initial results of OpT2mise showed that after six months, people with insulin-requiring type 2 diabetes who used MiniMed insulin pumps achieved better glucose control than those using MDI. Results after one year include:

- Glucose control improved significantly for all patients. Patients receiving MDI for the initial six months of the study were able to achieve an additional A1C reduction of 0.8% ($p<0.0001$) after switching to insulin pump therapy; both groups achieved an identical 1.2% reduction in A1C at the 12-month mark compared to the baselines.
- The clinical benefit from pump therapy was reproducible. The MDI group, which switched to insulin pump therapy after six months, experienced a similar reduction in A1C to the results seen in the original insulin pump group. Additionally, at the end of the continuation phase, participants who switched from MDI to insulin pump showed a 19.0% reduction in total daily insulin dose, making it equivalent in both treatment arms.
- Glucose control with pump therapy was sustained over 12 months. The original pump group had a further 0.1% reduction in A1C to attain a final 12-month value of 7.8%. There was no difference between groups in weight gain.

"At Medtronic Diabetes we are looking at how we can deliver greater freedom and better health for all people with diabetes, including those living with type 2," said Francine R. Kaufman, M.D., chief medical officer and vice president of global, clinical and medical affairs for Medtronic Diabetes. "The results of the OpT2mise trial, which is the largest study of its kind, will help us expand access to insulin pump therapy as a standard of care treatment for the growing number of insulin-taking type 2 diabetes patients so they can enjoy improved clinical outcomes."

About OpT2mise

The randomized, controlled OpT2mise study was sponsored by Medtronic and conducted with participation from 331 patients,

ranging in age from 30 to 75 years. Initial six-month study results comparing MiniMed insulin pump therapy to MDI were published in *The Lancet* in July 2014. During the six-month continuation phase of the study, the MDI group was switched to MiniMed pump therapy and follow-up of both groups was continued, making a total study period of 12 months.

About the Diabetes Group at Medtronic (www.medtronicdiabetes.com)
Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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1 UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complication in patients with type 2 diabetes (UKPDS 33). *Lancet.* 1998; 352:837-853.

2 The post trial monitoring results: 10 years follow up: Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HAW. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med.* 2008; 359:1577-1589.

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