

EuroPCR: Medtronic renal denervation system shows better blood pressure control with significantly more time in target range

Medtronic adds to SPYRAL HTN Global Clinical Program with late breaking clinical data for SPYRAL HTN-ON MED and GSR-DEFINE

DUBLIN and PARIS, May 17, 2022 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced data showing the benefits of the Symplicity Blood Pressure Procedure with the Symplicity Spyrals™ Renal Denervation (RDN) system on achieving target blood pressure level ranges. As part of the SPYRAL HTN Global Clinical Program, three-year data from SPYRAL HTN-ON MED and GSR-DEFINE were presented at EuroPCR 2022 as late-breaking clinical trials on May 17, 2022.

Time in target range (TTR) plays an important role in the management of many chronic diseases, such as diabetes and hypertension, measuring how well a parameter (e.g., blood pressure) is controlled in patients. Specifically, for hypertension, increasing TTR has been shown to be an independent predictor of reductions in cardiovascular risks, including stroke, heart attack, and death.¹ In a recent [consensus statement](#) by the Society for Cardiovascular Angiography & Interventions and the National Kidney Foundation, TTR is recognized as an effective measure of blood pressure control. As part of the statement, TTR is also noted as an important consideration to include as an endpoint in clinical trials and registries.

"The data presented today at EuroPCR provide meaningful insights into the benefits of RDN through a patient lens, looking at how much time they spend within a target BP range," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "This new data reinforces RDN's effectiveness as a complementary solution for achieving better blood pressure control and reducing cardiovascular risk."

SPYRAL HTN-ON MED 3-Year Data

Results from the first 80 patients in the SPYRAL HTN-ON MED trial demonstrate improved BP control with significantly higher TTR after radiofrequency RDN when compared to sham through three years, regardless of anti-hypertensive medications. TTR for patients treated with RDN (33.7% TTR) was nearly double of sham patients (18.8% TTR) through three years (p=0.023).

SPYRAL HTN-ON MED is a global, randomized, sham-controlled trial investigating the blood pressure lowering effect and safety of RDN with the radiofrequency-based Medtronic Symplicity Spyrals system in hypertensive patients prescribed one to three anti-hypertensive medications. The trial enrolled 80 typical uncontrolled hypertensive patients, randomized to RDN (n=38) or sham control (n=42).

The findings build upon the recent three-year safety and efficiency data [presented at ACC.22](#), which demonstrated safe and sustained blood pressure reductions through three years.

"By focusing on TTR in patients with uncontrolled hypertension, we can better understand how RDN can help control blood pressure and sustain a healthy level," said Dr. David Kandzari, chief, Piedmont Heart Institute and Cardiovascular Services and SPYRAL HTN-ON MED lead principal investigator. "These three-year data showed us that RDN nearly doubles the time patients spend in their target blood pressure range, regardless of anti-hypertensive medications, reinforcing the long-term benefit of the procedure."

GSR-DEFINE 3-Year Data

In the GSR-DEFINE study, improved blood pressure control after radiofrequency RDN is associated with lower risk of major adverse cardiovascular events (MACE) through three years in real-world patients. RDN patients spent 34.9% time in TTR through three years. There was also a 16% decrease in MACE associated with every 10% increase in TTR at 6 months.

GSR-DEFINE is a prospective, all-comer observational study in 222 sites across 42 countries, including 3,000 patients from the GSR study and enrolling up to an additional 2,000 patients.

"Results from this real-world patient setting closely mirror and build upon data from the SPYRAL HTN-ON MED trial showing improved blood pressure control with RDN. The findings from GSR-DEFINE further underscore the long-term safety and effectiveness of the Symplicity system in patients with uncontrolled hypertension, while also lowering their risk of major cardiovascular events," said Prof. Felix Mahfoud, M.D., cardiologist at Saarland University Hospital in Homburg, Germany, and member of the SPYRAL HTN executive committee.

About the Medtronic Symplicity Spyral™ Renal Denervation System

The Medtronic RDN procedure uses a minimally invasive procedure that delivers radiofrequency energy to specific nerves near the kidneys that can become overactive and cause high blood pressure. Approved for commercial use in more than 60 countries around the world, the Symplicity Spyral renal denervation system is limited to investigational use in the United States, Japan, and Canada.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow [@Medtronic](https://twitter.com/Medtronic) on Twitter and [LinkedIn](https://www.linkedin.com/company/medtronic).

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.

¹ Fatani N, Dixon DL, Van Tassell BW, Fanikos J, Buckley LF. Systolic Blood Pressure Time in Target Range and Cardiovascular Outcomes in Patients With Hypertension. *Journal of the American College of Cardiology* 2021;77:1290-1299. <https://doi.org/10.1016/j.jacc.2021.01.014>

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