Medtronic News

Medtronic study shows patients with high blood pressure are interested in an interventional procedure treatment option

New data from Medtronic Patient Preference study presented at TCT 2021; Medtronic adds to its clinical leadership for renal denervation with launch of the SPYRAL AFFIRM study

DUBLIN and ORLANDO, Fla., Nov. 4, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced findings from a new study of the Patient Preferences for the Treatment of Hypertension. The findings will be presented later today during the "What's Novel in Interventional Hypertension session" at the 33rd Transcatheter Cardiovascular Therapeutics (TCT 2021) conference, the annual scientific symposium of the Cardiovascular Research Foundation.

Medtronic also announced the initiation of the SPYRAL AFFIRM study, evaluating the long-term safety, efficacy, and durability of the Medtronic Symplicity™ Renal Denervation System in real-world patients with uncontrolled hypertension and comorbidities such as diabetes, isolated systolic hypertension, and chronic kidney disease.

Patient Preference in the Treatment of Hypertension: Interventional Treatments and Standard of Care

For the first time, new data presented at TCT 2021 quantified United States (U.S.) patient preferences for considerations of interventional procedures in the treatment of high blood pressure, including treatment mode, effectiveness and risks.

The study found that in exchange for treatment risks, patients on average would require a minimal acceptable benefit of less than 2.5mmHg reduction in office-based systolic blood pressure. Additionally, on average, patients indicated a tolerance of at least 20% risk of adverse events (such as a vascular injury or drug side effects) in exchange for being able to lower their office-based systolic blood pressure.

These findings suggest that despite the risks of an intervention, patients may accept lower blood pressure reductions than those observed in published literature of Medtronic Symplicity Spyral Renal Denervation procedure[1,2]. Additionally, patients may be willing to tolerate risks higher than those observed in peer-reviewed published studies[3] of Symplicity Spyral.

The study also concluded that blood pressure reduction was the most important driver of patient preference over all other attributes like medication burden and treatment (including interventional treatment-related) risks. When applying this model to a patient population who is interested in an interventional procedure without medication, up to 76.5% of patients would be willing to consider an interventional approach such as RDN if they achieve a 10mmHg reduction in office-based systolic blood pressure. Including the maximum acceptable risk of 20%:

- 76.5% of patients would be willing to consider an interventional approach such as RDN with reductions in office blood pressure anticipated at 10 mmHg.
- 24.3% of patients would be willing to consider an interventional approach such as RDN with reductions in office blood pressure anticipated at 5 mmHg.
- 6.9% of patients would be willing to consider an interventional approach such as RDN with reductions in office blood pressure anticipated at 2.5 mmHg, the minimal acceptable benefit.

"This novel, patient preference study is particularly valuable for a new procedure like renal denervation, because it demonstrates that for patients, lowering blood pressure, even by a small amount, is meaningful,"

said Dr. Michael Weber, professor of cardiovascular medicine at State University of New York, Downstate Medical Center. "For the first time, these results give us quantitative insights into hypertension treatment preferences - importantly, patients are very open to considering a medical intervention procedure, such as RDN, with demonstrated improvements in the control of their high blood pressure."

The study, which was designed based on the FDA Guidance for Patient Preference Information, surveyed 400 individuals in the U.S. who have high blood pressure (physician confirmed systolic office-based blood pressure greater than 140 mmHg), who were on up to three anti-hypertensive medications and were not previously involved in a SPYRAL HTN study. The study uses a statistical method called a discrete choice experiment, often used to compare individuals' preferences among two or more alternatives.

"The patient preference insights, combined with the breadth of real world and randomized sham controlled trials we have for renal denervation, are aligned with the recent clinical consensus from the European Society of Hypertension, Society for Cardiovascular Angiography and Interventions, and National Kidney Foundation that reinforce RDN as a potential treatment option for patients," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "Patient preference data will be important to help physicians understand patients' acceptable benefits and risks related to minimally invasive procedures for the treatment of hypertension."

SPYRAL AFFIRM Study Launch

Separately, Medtronic announced that the first patient was enrolled at Piedmont Heart Institute in Atlanta, Ga. for the SPYRAL AFFIRM clinical study. Using a performance goal, this clinical study will enroll 1,000 real-world patients with uncontrolled hypertension and associated comorbidities, such as isolated systolic hypertension, diabetes, and chronic kidney disease. SPYRAL AFFIRM will follow these patients for three years. This investigational device exemption trial was approved by the U.S. Food and Drug Administration (FDA) in June 2021 and will be conducted at 100 sites globally.

"Through the strong investment in our clinical program, the AFFIRM study will expand RDN research into a variety of patient groups," said Weidman. "The AFFIRM clinical study adds to our body of evidence for RDN and will help us further answer questions about the use of this procedure in more complex, real world patients such as those with isolated systolic hypertension, diabetes and chronic kidney disease."

The SPYRAL AFFIRM clinical study is part of the SPYRAL HTN Global Clinical Program, adding to the safety and efficacy data for RDN. Along with the real-world data from the Global Symplicity Registry,[4] when combined with commercial experience, there have been more than 20,000 procedures performed with Medtronic RDN technology. The clinical program is backed by the most rigorous and extensive patient experience studied in the presence[2] and absence[1] of medication and in patients with high baseline cardiovascular risk.[4]

About the Medtronic Symplicity™ 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 all. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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] Kandzari et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomised trial. The Lancet, 2018

[2] Böhm M, Kario K, Kandzari DE, Mahfoud F, Weber MA, Schmieder RE, et al., SPYRAL HTN-OFF MED Pivotal Investigators. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. The Lancet 2020; 395:1444–1451.

[3] Townsend et al. Review and meta-analysis of renal artery damage following percutaneous renal denervation with radiofrequency renal artery ablation. EuroIntervention 2020; 16: 89-96.

[4] Mahfoud F, et al. Renal Denervation in High-Risk Patients with Hypertension. J Am Coll Cardiol. 2020; 75(23): 2879-88.

Contacts:

Krystin Hayward Leong	Ryan Weispfenning
Public Relations	Investor Relations
+1-508-298-8246	+1-763-505-4626

SOURCE Medtronic plc

---

https://news.medtronic.com/2021-11-04-Medtronic-study-shows-patients-with-high-blood-pressure-are-interested-in-an-interventional-procedure-treatment-option