Medtronic News

Study Published in The New England Journal of Medicine Demonstrates Patients Experience Fewer Disruptions to Dialysis Therapy When Treated with Medtronic Drug-Coated Balloon

Results Showed IN. PACT™ AV DCB Is Safe, Reduces Reinterventions, and Helps Maintain Dialysis Access for Those Living with End-Stage Renal Disease

DUBLIN, Aug. 19, 2020 (GLOBE NEWSWIRE) -- Medtronic announced today the publication of the primary endpoint results from the IN.PACT AV Access trial in *The New England Journal of Medicine*.[1] The results reinforce that the IN.PACT™ AV drug-coated balloon (DCB) limits the number of reinterventions needed to maintain blood flow (patency) in patients with end-stage renal disease (ESRD) who have arteriovenous (AV) fistulae, leading to fewer interruptions to their dialysis therapy.

Nearly 2.5 million ESRD patients worldwide regularly undergo hemodialysis[2] — many of whom require AV fistulae in order to receive continuous dialysis. For these patients, AV fistulae serve as lifelines, and maintaining access to these sites is essential. Vessels that feed the access site can narrow (restenose) over time, however, and patients often undergo multiple maintenance procedures per year to restore access site function. The need for frequent reinterventions can result in repeated hospital visits and significant disruptions to critical hemodialysis care. Therefore, by being able to maintain access site patency, patients may experience longer periods of successful, uninterrupted dialysis.

“The six-month data demonstrate that with IN.PACT AV DCB, we can cut the number of reinterventions required to maintain vessel patency in half. This technology may positively impact patients’ quality of life, and demonstrate meaningful reductions in projected costs to the healthcare system,” said Robert Lookstein, M.D., M.H.C.D.L., U.S. study principal investigator, professor of radiology and surgery, executive vice-chair in the Department of Diagnostic, Molecular, and Interventional Radiology at the Icahn School of Medicine at Mount Sinai in New York, New York. “Right now, this is very important for ESRD patients on hemodialysis, who are at especially high risk of acquired infections. This technology may have the potential to allow these patients to experience continued, uninterrupted access to life-saving dialysis care, including fewer hospital visits to get their access sites maintained.”

The IN.PACT AV Access study is a randomized controlled trial (RCT), which has enrolled 330 subjects at 29 sites in United States, Japan, and New Zealand. Notably, the IN.PACT AV DCB is the first and only approved DCB for the treatment of failing AV access to meet both its primary safety and effectiveness endpoints. Through six months, the rate of target lesion primary patency was substantially higher in participants treated in the IN.PACT AV DCB group compared to those in the PTA control group (82.2% vs. 59.5% ($p<0.001$)). Kaplan-Meier estimates for this dataset indicate:

- 86.1% primary patency rate in the IN.PACT AV DCB group compared to 68.9% in the PTA control group (log-rank $p<0.001$) of the target lesion at 180 days.
- 81.4% primary patency rate in the IN.PACT AV DCB group compared to 59.0% in the PTA control group (log-rank $p<0.001$) through 210 days.

Furthermore, patients treated with IN.PACT AV DCB required 56% fewer reinterventions to maintain lesion patency as compared to those treated with standard PTA through six months.

For its primary safety endpoint, the IN.PACT AV DCB group showed non-inferiority versus the PTA control group in the rate of severe adverse events (SAEs) involving the AV access circuit within 30 days. Through 12 months, the mortality rate was comparable between the IN.PACT AV DCB group and the PTA control group (9.4% vs.

9.6%, log-rank p=0.931).

“When treated with standard PTA, ESRD patients requiring AV fistula maintenance often have to undergo anywhere from 1-3 access procedures per year. This, in addition to their multiple weekly dialysis appointments, results in even more time spent in a healthcare setting,” said Terry Litchfield, M.P.H., president of Access Solutions, an organization focused on patient advocacy related to vascular access services. “These newly-published data on IN.PACT AV DCB not only show promise in keeping people living with ESRD out of the hospital for longer, they also demonstrate that using this DCB will reduce the number of interventions a patient will need each year, thus avoiding the time and expense of additional procedures to keep their dialysis access working well.”

“The publication of the six-month results in *The New England Journal of Medicine* adds to the body of evidence of the safety and clinical benefit of this paclitaxel-coated platform,” said Mark Pacyna, vice president and general manager of the Peripheral Vascular business, which is part of the Cardiac and Vascular Group at Medtronic. “The IN.PACT AV DCB extends the time between reinterventions and reduces hospital visits. These clinical benefits are critically important for this patient population, especially in today’s environment, and Medtronic is committed to helping people with ESRD maintain access to life-saving dialysis.”

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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] Lookstein RA, et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. N Engl J Med 2020;383:733-42. DOI: 10.1056/NEJMoa1914617

[2] MedTech Europe. *Improving dialysis for patients and health systems in community and home care*. https://www.medtecheurope.org/wp-content/uploads/2015/10/6-Evidence-report-dialysis-FINAL.pdf

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https://news.medtronic.com/2020-08-19-Study-Published-in-The-New-England-Journal-of-Medicine-Demonstrates-Patients-Experience-Fewer-Disruptions-to-Dialysis-Therapy-When-Treated-with-Medtronic-Drug-Coated-Balloon