Medtronic News

Independent Stent Imaging Study Shows Excellent Healing Profile with Resolute Onyx DES in Complex Patients with Coronary Artery Disease

Onyx 1-Month OCT Study Provides Potential Insights on DAPT Duration in Complex Patients Following Stent Implantation

DUBLIN and PARIS- May 24, 2018 - Investigators today unveiled clinical data from the independently run Onyx 1-Month OCT Study, which showed strong early vessel healing in a patient population that contained a high percentage of patients with complex coronary artery disease who were implanted with the Resolute Onyx(TM) DES at one-month follow-up. Presented at the EuroPCR Annual Meeting in Paris, data from 15 patients - including 13 with acute coronary syndrome (ACS) - were evaluated using Optical Coherence Tomography (OCT), a light-based intracoronary imaging that provides extremely high-quality images of the coronary wall, especially of the structures closest to the vessel lumen.

In the Onyx 1-Month OCT Study, patients implanted with the Resolute Onyx DES demonstrated an excellent early healing profile with an average of 88 percent of struts covered by neointimal formation (new cell growth over stent struts) and 92.3 percent of the total stented area showing complete strut coverage at one month, which includes the covered areas in between the struts.

"The signal of early healing is crucial for patients who may need to interrupt or discontinue dual anti-platelet therapy (DAPT) within a short period of time after receiving a stent," said Elvin Kedhi, M.D., Ph.D., interventional cardiologist at Isala Hartcentrum in Zwolle, the Netherlands, one of the lead principal investigators of the Onyx 1-Month OCT Study. "These data help expand the growing body of clinical evidence that may support physicians in tailoring DAPT regimens for complex patients."

The Onyx 1-Month OCT Study is the latest of several Medtronic funded studies helping to generate additional clinical evidence to reinforce the understanding of healing and shorter DAPT regimens in complex patients. Last year, Medtronic announced the Onyx ONE Global Study, a randomized clinical trial that will compare one-month DAPT between two DES for the first time, which is currently enrolling. A similar study will launch in the U.S. and Japan later this calendar year and will help inform DAPT guidelines for newer-generation DES that currently favor bare-metal stents (BMS) for patients at an increased risk of bleeding who might require a shorter DAPT regimen.

In a separate analysis presented at the EuroPCR meeting, new data from the DAPT-STEMI trial in patients treated with the Resolute Integrity DES, showed excellent results in a prospective prespecified registry which evaluated all patients after six months of DAPT duration, prior to randomization. At six months, the patient oriented composite primary endpoint (all-cause mortality, any myocardial infarction (MI), any revascularization, stroke and TIMI major bleeding (net NACCE)) occurred in 4.2 percent of patients, with low rates of target lesion revascularization (1.1 percent) and stent thrombosis (0.7 percent).

"We are committed to generating meaningful clinical evidence to help inform physician decision making and guidelines around the use of newer-generation DES in complex patients," said, Dave Moeller, vice president and general manager of the Coronary and Renal Denervation business, which is part of the Cardiac and Vascular Group at Medtronic. "These results reinforce our commitment to studying one-month DAPT in studies like the Global Onyx ONE Study which is currently enrolling around the world."

The Resolute Onyx DES with thinner struts is the first and only DES to feature Core Wire Technology, an evolution of Continuous Sinusoid Technology (CST). CST is a unique Medtronic method of stent manufacturing, which involves forming a single strand of cobalt alloy wire into a sinusoidal wave to construct a stent. This enables greater deliverability and conformability to the vessel wall. With Core Wire Technology, a radiopaque inner core is incorporated within the cobalt alloy

wire to enhance visibility for accurate stent placement. Core Wire Technology also enables thinner struts while maintaining structural strength.

The Resolute Onyx DES received CE (Conformité Européene) Mark in September 2014 and FDA approval in April 2017.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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 84,000 people worldwide, serving physicians, hospitals and patients in more than 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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