Medtronic News

In Trial of Rivals, Medtronic's Resolute Integrity Stent Outperforms Promus Element Stent on Longitudinal Strength

(Thomson Reuters ONE via COMTEX) --Presented at TCT and Published by The Lancet, Results of DUTCH PEERS Negate Notion of

Class Effect with Structural Stability of 'More Flexible and Highly Deliverable Devices'

SAN FRANCISCO -- Oct. 31, 2013 -- In the first head-to-head randomized controlled trial of "third-generation" durable-polymer drug-eluting stents for the treatment of coronary artery disease in an "all-comers" patient population, the Resolute Integrity drug-eluting stent (DES) from Medtronic, Inc. (NYSE: MDT) and the Promus Element DES from Boston Scientific Corp. performed similarly on all measures except longitudinal strength, which favored the Medtronic device.

One-year results from DUTCH PEERS, which included a pre-specified assessment of this important device characteristic, were presented today at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium during the late-breaking clinical trials session and simultaneously published by The Lancet. They show a statistically significant difference in longitudinal stent deformation (length-wise distortion or shortening of the device inside the artery after deployment) between the two devices at one year of follow-up ($p=0.002$): nine occurrences (1.0 percent) with the platinum-chromium Promus Element stent platform ($n=905$) vs. zero occurrences (0.0 percent) with the cobalt-alloy Resolute Integrity stent platform ($n=905$).

"A potential trade-off with the novel, flexible designs of third-generation stent platforms was thought to be reduced longitudinal device stability," said lead author and presenter Clemens von Birgelen, M.D., Ph.D., co-director of the Department of Cardiology at Thoraxcentrum Twente and professor of cardiology at the University of Twente in the Netherlands. "However, our study did not find such a trade-off with the Resolute Integrity DES."

In contrast to the finding on longitudinal strength, DUTCH PEERS found no statistically significant differences at one year between the Resolute Integrity and Promus Element stents on the composite primary endpoint of target vessel failure (6.1 percent vs. 5.2 percent, $p=0.42$). Individual components of TVF -- cardiac death, target vessel myocardial infarction, and target vessel revascularization -- were also low and similar in both groups. Additionally, the incidence of definite/probable stent thrombosis for both groups was similarly low (0.6 percent vs. 0.9 percent respectively, $p=0.40$), and there was no definite stent thrombosis in either group after three months following stent implantation.

DUTCH PEERS, also known as TWENTE II, adds to the growing body of evidence from "all-comers" stent studies, which include very few exclusion criteria to ensure applicability of their results to real-world clinical practice. Previously, at TCT11, Prof. von Birgelen unveiled the results of the original TWENTE trial, another head-to-head all-comers study, which found excellent clinical results with the second-generation Resolute DES and no significant differences compared to Abbott Laboratories' Xience V DES at one year. "The strong clinical performance of the Resolute Integrity DES in DUTCH PEERS is very consistent with the results of the Resolute DES that were found in TWENTE," he said.

In collaboration with leading clinicians, researchers and scientists, 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 worldwide.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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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Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1738926
