Medtronic News

For Bifurcation Lesions in Coronary Arteries, Medtronic's Resolute Stent Delivers Strong Long-Term Results

Three Analyses Presented at EuroPCR Demonstrate Device's Durability in Addressing Common Clinical Challenge

PARIS -- May 22, 2013 -- Addressing one of the most common clinical challenges in the treatment of complex coronary artery disease, three separate analyses on the program for EuroPCR this week show how strongly the Resolute drug-eluting stent from Medtronic, Inc. (NYSE: MDT) performs in coronary bifurcation lesions over the long term.

Bifurcation lesions occur when plaque builds up around the junction of two coronary arteries -- where one branches off another. Accounting for approximately 20 percent of all percutaneous coronary interventions1, bifurcated lesions are challenging to treat because of anatomical variations involving multiple vessels, including the procedural challenges inherent in accessing the side branch. As a result, they are typically associated with lower procedural success rates, more frequent revascularizations, and worse clinical outcomes.

For one of the largest clinical analyses on bifurcation lesions ever performed, investigators pooled the results of nearly 3,500 "real-world" patients who received a Resolute stent as participants in two studies with very few exclusion criteria --

RESOLUTE All-Comers and RESOLUTE International. Dr. Ran Kornowski of the Rabin Medical Center and Tel Aviv University in Israel will present the analysis at EuroPCR on Thursday.

From a total of 3,489 patients, 703 patients (20 percent) presented with at least one bifurcation lesion. At three years of follow-up, the Resolute drug-eluting stent showed excellent clinical results, with no statistical differences between patients with and without bifurcation lesions. Rates of clinically-driven target lesion revascularization (i.e. repeat procedure), for example, were low and comparable for both groups: 6.9 percent versus 5.4 percent (p=0.104), respectively.

Approved the U.S. Food and Drug Administration in 2012, the Resolute Integrity stent is not indicated for the treatment of bifurcation lesions in the United States. Its CE (Conformité Européene) mark labeling, however, does include an indication for bifurcation lesions.

Confirmatory Study

In a separate, independent "real-world" multicenter registry that included nine sites in Italy, 527 patients with bifurcation lesions were treated with the Resolute stent using mainly the "provisional-T-stenting technique."

Presented today by Dr. Francesco Burzotta from the Catholic University of the Sacred Heart in Rome, two-year follow-up results from this confirmatory study also showed low target lesion revascularization rates for these patients at 5.1 percent. Of note, the long-term clinical outcome was similarly good across patients with different anatomical complexity of treated bifurcation lesions.

"Bifurcations remain a common challenge in today's practice due to anatomical variability and lesion complexity," said Dr. Burzotta. "Nevertheless, the 'provisional-T-stenting technique' may be facilitated by specific technical characteristics of some contemporary drug-eluting stents. Results from multiple analyses demonstrate that use of the Resolute stent to treat bifurcated lesions may be associated with promising long-term clinical results in a wide variety cases."

One potential explanation that supports the strong clinical data on the Resolute stent in bifurcations is the device's conformability and wall apposition even after side branch treatment, which represents a critical success factor in treating these complex and highly variable lesions.

In another EuroPCR presentation, Peter Mortier, Ph.D., from Ghent University in Belgium, shared the results of an independent analysis comparing different drug-eluting stent platforms in bifurcation lesions using computer models. Dr. Mortier's analysis found that the Resolute Integrity stent showed significantly less stent-strut malapposition (i.e. lack of contact between stent struts and artery wall) compared to the Promus Element and Xience Prime stent platforms from Boston Scientific Corp. and Abbott Laboratories, respectively.

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.

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1 Based on the bifurcation rate in large, recent all-comer trials and registries, including RESOLUTE All Comers (17%), RESOLUTE International (18%), TWENTE (26%), LEADERS (29%), and NOBORI 2 (24%).

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