Medtronic Stent Successfully Treats Long Lesions and Small Vessels, Two Characteristics Typical of Patients with Diabetes, in Multiple Studies

Medtronic

For the treatment of long lesions and small vessels –– two challenging characteristics of coronary artery disease commonly found in patients with diabetes –– the Resolute drug-eluting stent from Medtronic, Inc. (NYSE: MDT) delivered successful clinical results, according to new data presented at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium.

“The Resolute stent continues to provide consistent and favorable clinical results,” said Ronald Caputo, M.D., director of cardiac services and cardiology research at St. Joseph’s Hospital in Syracuse, N.Y. “Patients with long lesions and small vessels are among the most difficult to treat, and for those who also have diabetes it can be even more challenging.”

Long Lesions (One-Year Follow-Up)
For the long-lesion cohort, data on 222 patients from the RESOLUTE US and RESOLUTE Asia clinical studies who received a 38 mm Resolute stent for the treatment of coronary lesions less than or equal to 35 mm in length showed a one-year target lesion failure (TLF) rate of 5.4 percent, with low rates of clinical events and no instances of late stent thrombosis (0.0 percent). (Target lesion failure is a composite endpoint that includes clinically-driven target lesion revascularization, cardiac death and target-vessel myocardial infarction.) The 38 mm Resolute stent is not currently available for commercial distribution in the United States.

This pre-specified analysis contributes to Medtronic’s submission to the U.S. Food and Drug Administration (FDA) for approval of the 38 mm Resolute Integrity drug-eluting stent, a length for this device that is considered investigational in the United States. The company’s approval application for the 38 mm stent is currently under review by the FDA. Core sizes of the Resolute Integrity stent received FDA approval in February.

Of the patients in this cohort, nearly 38 percent had diabetes mellitus, and their results were similar to the patients without diabetes. For the diabetes patients, the one-year TLF rate was 6.0 percent, with similarly low clinical event rates and no instances of stent thrombosis (0.0 percent). Additionally, the one-year rate of clinically-driven target lesion revascularization in the diabetes patients was a low 2.4 percent. (Target lesion revascularization means a repeat procedure was clinically necessary to treat the narrowed arterial segment again.)

Small Vessels (Two-Year Follow-Up)
For the small-vessel cohort, data on 1,956 patients were pooled from the RESOLUTE, RESOLUTE All Comers, RESOLUTE International, RESOLUTE US and

RESOLUTE Japan clinical studies who received a Resolute stent for the treatment of coronary lesions of no greater than 2.5 mm in diameter.

The data on patients with small vessels from these studies showed a two-year TLF rate of 10.1 percent, similar to the 3,174 patients in these same studies with larger vessels (8.7 percent, p=0.53). They also showed low rates of clinical events and stent thrombosis for both groups at two years, with no statistical differences between the two.

Of the patients in this cohort, more than one-third had diabetes mellitus, and their results were similar to those without diabetes. For the 672 diabetes patients, the two-year TLF rate was 11.2 percent; for the 1,284 patients without diabetes, it was 9.6 percent (p=0.28). Two-year rates of clinically-driven target lesion revascularization were also very similar for the two groups: 6.3 percent for patients with diabetes; 4.8 percent for patients without diabetes (p=0.19). In addition, the two-year rates of stent thrombosis were low and also similar: 0.9 percent for diabetes patients; 0.8 percent for non-diabetes patients (p=0.73).

Dr. Caputo is an investigator in RESOLUTE US and presented the small vessel data. Shirish Hiremath, M.D., director of the cardiac catheterization laboratory at Ruby Hall Clinic in Pune, India, is an investigator in RESOLUTE Asia and presented the long lesion data.

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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