American College of Cardiology Journal Publishes Outcomes of Diabetes Patients Treated with Medtronic's Resolute Stent

The Associated Press

Implanted Medical Device for Coronary Artery Disease Performed As Well In Study Subjects With Diabetes Who Were Not Taking Insulin As In Those Without Diabetes

MINNEAPOLIS -- April 15, 2013 -- The current issue of JACC: Cardiovascular Interventions, a peer-reviewed journal published by the American College of Cardiology, includes an article that describes how the Resolute Integrity drug-eluting stent from Medtronic, Inc. (NYSE: MDT) became the first and only device of its kind to be approved by the U.S. Food and Drug Administration (FDA) with a specific indication for treating the coronary artery disease of patients with diabetes mellitus.

A common comorbidity of coronary artery disease, diabetes affects approximately one-third of patients who receive coronary stents and historically has been associated with adverse clinical outcomes. New research presented in the journal article, however, shows that treatment with the Resolute drug-eluting stent led to similarly positive outcomes for diabetes patients who were not taking insulin and for patients without diabetes. It was sponsored by Medtronic.

Titled "Clinical Outcome of Patients With and Without Diabetes Mellitus After Percutaneous Coronary Intervention with the Resolute Zotarolimus-Eluting Stent" (R-ZES), the article presents the results of two separate analyses of patient-level data from the global RESOLUTE clinical program, which enrolled a total of 5,130 patients who received a Resolute drug-eluting stent as participants in one of five studies conducted in the United States and internationally.

The authors' conclusions state: "The R-ZES is safe and effective in patients with diabetes. Long-term clinical data of patients with non-insulin-treated diabetes are equivalent to patients without diabetes. Patients with insulin-treated diabetes remain a higher risk subset."

Two Analyses, Similar Findings
One analysis reported in the article evaluated the performance of the device in the 878 standard-risk diabetes patients who received it. Prospectively determined in conjunction with the FDA, it set a 12-month target vessel failure (TVF) rate of 14.5 percent as a performance goal.

The actual rate of TVF at 12 months among these standard-risk diabetes patients was significantly lower at 7.8 percent ($p<0.001$), demonstrating superiority of the Resolute drug-eluting stent over first-generation devices in this patient subset. The results of this analysis led to FDA approval of a unique diabetes indication for the

Resolute Integrity drug-eluting stent in February 2012.

This analysis also found low and comparable rates of target lesion failure (TLF) at two years in the patients with non-insulin-treated diabetes when compared to the patients without diabetes (8.0% vs. 7.1%). In addition, it found a predictably higher two-year TLF rate in the patients with insulin-treated diabetes (13.7%).

(Target vessel failure is a composite endpoint that includes cardiac death, myocardial infarction and revascularization attributable to any part of the stented vessel; target lesion failure includes the same components, but only as attributable to the stented segment of the vessel.)

Another analysis reported in the article evaluated the cumulative incidence of TLF at two years for all 5,130 patients, many of whom had complex coronary artery disease.

For this analysis, the patients were first divided into two groups: those with diabetes (1,535; 30%) and those without diabetes (3,595; 70%). The diabetes patients were then divided into two groups: those who were taking insulin (455; 30%) and those who were not taking insulin (1,080; 70%).

This analysis yielded a similar finding. Specifically, it found low and comparable two-year rates of TLF in patients with non-insulin-treated diabetes and patients without diabetes (8.9% vs. 8.4%) -- and a predictably higher rate of TLF at two years in patients with insulin-treated diabetes (16.7%).

"These two analyses offer interventional cardiologists worldwide increased confidence when making treatment decisions about the coronary artery disease of patients with diabetes mellitus, who have historically experienced worse clinical outcomes following coronary stent procedures," said lead author Prof. Dr. Sigmund Silber, director of the Heart Center at the Isar in Munich, Germany.

The strong performance of the Resolute drug-eluting stent in patients with diabetes -- both in clinical studies and real-world clinical practice -- advances the growing body of evidence that warranted the device's unique diabetes indication in the United States.

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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