Medtronic News

Women Undergoing TAVI Using the Medtronic CoreValve® System Have Similar Survival Benefit as Men

Rigorous Trial Design and Monitoring Provides New Insight to Outcomes for Men and Women with Aortic Stenosis

PARIS--(BUSINESS WIRE)--May. 17, 2012-- Medtronic, Inc. (NYSE: MDT) today announced new results from the Medtronic CoreValve ADVANCE Study, which found that women and men benefitted similarly from the Medtronic CoreValve® System. The study, presented at EuroPCR 2012, evaluated patients who were at high-risk for surgical aortic valve replacement. The Medtronic CoreValve System is currently limited to investigational use in the United States.

The gender analysis, a secondary-endpoint evaluation in the real-world CoreValve ADVANCE Study, found that survival rates were nearly identical between genders, with no statistical differences in 30-day and 6-month all-cause mortality, cardiovascular mortality or the 30-day MACCE endpoint (Major Adverse Cardiac & Cerebrovascular Events, a composite of all-cause mortality, myocardial infarction, emergent cardiac surgery or percutaneous re-intervention, and stroke).

Overall, patients experienced low 30-day stroke rates (2.9 percent overall), with the combined stroke rates of major and minor strokes being very low (major 1.2 percent, and minor 1.7 percent). However, female patients experienced a statistically higher rate of strokes (4.4 percent vs. 1.4 percent; p-value <0.01), major vascular complications (14.1 percent vs. 7.1 percent; p-value <0.01) and major bleeding (5.0 percent vs. 3.1 percent; p-value <0.01). For minor stroke between genders, and for major strokes between genders, differences were not significant, though there was a trend for women to have more minor strokes than men.

“This study is an important contribution to the growing base of research on TAVI, and sheds light on the unique needs for managing severe aortic stenosis in women,” said Patrizia Presbitero, M.D., director of Interventional Cardiology at Hospital Humanitas Rozzano in Milan and an investigator in the CoreValve ADVANCE Study, and a professional development co-chair and member of the Leadership Council of WIN (Women in Innovations/Society for Cardiovascular Angiography and Interventions, SCAI). “We need to know more about gender differences to effectively treat patients with heart disease in a more specific way, taking into account those differences that can affect treatment.”

Women and men benefited similarly from the CoreValve System even though women (51 percent of patients) and men (49 percent of patients) had different risk profiles. Specifically, at the time of enrollment, women as compared to men were:

- Older than males (82.2 years vs. 79.9 years; p-value <0.001);
- Had higher average gradients (47.6 vs. 43.5 mmHg; p-value <0.001) and peak gradients (79.0 vs. 72.5 mmHg; p-value <0.001), a measure of blood flow across the valve;
- Had less coronary artery disease (46 percent vs. 70 percent; p-value <0.001); and
- Were prescribed fewer cardiovascular medications, including cholesterol-lowering medications (p-value 0.002) and statins (p-value 0.013).

“The robust ADVANCE trial provides a compelling discovery that the CoreValve System is an excellent therapeutic option for both men and women, and it helps us begin to consider how men and women present differently prior to implant and might be managed accordingly,” said Axel Linke, M.D., professor of medicine at Universitat Leipzig Herzzentrum in Leipzig, Germany and principal investigator of the ADVANCE clinical trial. “An important next step will be to further evaluate why stroke events were more common for women, including the

possible role of medications which were prescribed less frequently for women in this study."

The ADVANCE study is one of the largest multicenter transcatheter aortic valve implantation (TAVI) trials to date, with 1,015 patients consecutively treated at 44 experienced TAVI centers in 12 countries. Clinical endpoints were calculated according to Valve Academic Research Consortium (VARC) standardized definitions. All data were independently monitored, all adverse events related to the primary endpoints were adjudicated by an independent Clinical Events Committee (CEC) consisting of experienced cardiac surgeons and interventional cardiologists, and all cerebrovascular events (including stroke and other events) were adjudicated by an independent neurologist using neuroimaging and systematic NIH Stroke Scale assessments.

The Medtronic CoreValve System received CE (Conformite Europeenne) Mark in 2007 for the treatment of patients deemed at high or extreme risk for surgery. Since then, it has been implanted in more than 27,000 people in more than 50 countries outside the U.S. The CoreValve System is available in three sizes (26mm, 29mm and 31mm), and is the only transcatheter aortic valve implantation system approved for direct aortic or subclavian access.

Worldwide, approximately 300,000 people have been diagnosed with symptomatic, severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery.1

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.

1*Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?* Bernard Iung et al. Eur Heart J (December 2005) 26(24): 2714-2720.

Source: Medtronic, Inc.

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