Medtronic News

Medtronic CoreValve Data Demonstrate Favorable Cost Effectiveness Compared to Open-Heart Surgery in High Risk Patients

Cost Effectiveness of Self-Expanding Valve Driven by Improved Quality of Life Benefit and Superior One-Year Survival Rates over Surgical Aortic Valve Replacement

WASHINGTON, D.C., and MINNEAPOLIS - Sept. 13, 2014 - In the first-ever in-trial cost effectiveness analysis of transcatheter aortic valve replacement (TAVR) for patients at high risk for surgery, investigators today revealed new data demonstrating the cost effectiveness of the CoreValve® System from Medtronic, Inc. (NYSE: MDT) for high risk patients with severe aortic stenosis. The economic analysis used data from the CoreValve U.S. Pivotal Trial's study of high risk patients, which is the only head-to-head study to show the superiority of TAVR to traditional surgical aortic valve replacement (SAVR) at one year. The new data were presented during a late-breaking session at Transcatheter Cardiovascular Therapeutics (TCT) 2014.

In this analysis, TAVR patients used fewer healthcare resources related to the procedure time, ICU time, hospital length-of-stay and need for rehabilitation services at discharge ($p=<0.001$ for all measures including procedure time of 61+/-35 minutes TAVR versus 221+/-85 minutes SAVR; ICU time of 3.1 days TAVR versus 4.7 days SAVR; hospital length-of-stay of 8.1 days TAVR versus 12.5 days SAVR; and 23 percent TAVR vs. 44 percent SAVR for rehab services at discharge). While quality of life (QOL) was similar for TAVR and SAVR patients at 6-months and 1-year, TAVR patients reported improved QOL at 1-month.

Initial hospital costs were higher with TAVR by approximately $11,000 per patient, largely driven by the higher cost for a TAVR valve compared to a SAVR valve, which was not fully offset by cost savings due to reduced length-of-stay, more efficient procedures, and reduced use of rehab services. However, TAVR with the CoreValve System added 0.24 life years and 0.20 quality-adjusted life years (QALY) per patient at a lifetime incremental cost of approximately $13,700. Across all access routes, the incremental cost effectiveness ratio (ICER) for the CoreValve System was $57,000 per life year gained and $67,000 per QALY. Specific to the iliofemoral access route, used in 85 percent of patients in this analysis, the CoreValve System was associated with an ICER of $48,330 per life year gained and $55,534 per QALY.

"It's encouraging to see that for patients at high risk for surgery, TAVR with the CoreValve System provides a greater chance for a longer and higher quality of life, likely due to faster recovery from the procedure, at a reasonable cost," said Matthew Reynolds, M.D., of Lahey Hospital and Medical Center, Burlington, Mass., who presented the results. "In an age where healthcare costs are under increased scrutiny, it is especially important and reassuring to know that this new self-expanding valve also is cost effective for the U.S. healthcare system. And we can expect costs associated with length-of-stay, complications and ICU days to decrease as this therapy transitions into commercial use and implanters gain greater experience."

The cost effectiveness analysis examined total one-year costs for all patients randomized in the High Risk Study (n=795) (from the perspective of the U.S. healthcare system), including medical resource utilization for all patients, hospital bills and health state utilities measured at one, six and 12 months. These data were then combined with patient-level survival and quality of life data to estimate the ICER of TAVR versus SAVR, in terms of cost per year of life gained and cost per QALY, gained over a lifetime horizon. The investigational sites in this analysis did not have prior TAVR experience, but did have extensive SAVR experience.

The CoreValve System was approved by the U.S. Food and Drug Administration (FDA) in June 2014 for patients at high risk for surgery based on data that showed the CoreValve System was associated with improved survival over surgery (85.8 percent vs. 80.9 percent), with no increased risk of stroke at one year.

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.

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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