Fewer deaths with self-expanding TAVR versus surgery at one year

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Transcatheter aortic valve replacement with a self-expanding valve prosthesis for the first time has demonstrated significantly lower death rates at one year compared with conventional surgical valve replacement in high-risk patients with severe aortic stenosis, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session.

Worldwide, an estimated 300,000 people have severe aortic stenosis – a faulty valve in the main artery carrying blood out of the heart – and roughly a third of them are deemed unable to withstand the standard treatment of open-heart surgery to replace the valve. But if the condition is left untreated, risk of death is 25 percent the first year after symptoms appear and rises to 50 percent the second year. Replacement valves delivered by a catheter, usually through the groin or chest, have been developed as a less invasive alternative to open-heart surgery.

The CoreValve U.S. Pivotal High Risk Trial enrolled patients with an assessed increased risk of death from aortic valve surgery. Of 795 patients randomly assigned to valve replacement by catheter or surgery, 747 patients underwent one of the procedures: 390 in the transcatheter aortic valve replacement (TAVR) arm and 357 in the surgical aortic valve replacement arm. The average age was about 83 years in both groups. The results exceeded the initial non-inferiority goal and, by pre-design, then moved on to a superiority analysis. Death rates at 30 days were not significantly different, with a 3.3 percent death rate for TAVR and 4.5 percent for surgery. A significant difference emerged at the one-

year primary endpoint of all-cause mortality: 14.2 percent for TAVR with CoreValve compared with 19.1 percent for surgical replacement.

"This is the first prospective study of any device that suggests TAVR is superior to [surgery] in a predefined population of patients, and that's a provocative finding," said David H. Adams, M.D., professor and chairman of the Department of Cardiothoracic Surgery at Mount Sinai Medical Center and co-principal investigator of the study. He emphasized the "outstanding outcomes" in the surgical arm: "The low mortality rates with conventional surgery far exceeded the predicted mortality according to the Society of Thoracic Surgeons predictive model. In order to pass a superiority threshold, transcatheter treatment with the CoreValve device had to exceed excellent surgical outcomes."

Exploratory analyses also showed the one-year rate for heart attack, stroke or related death was significantly lower for TAVR at 20.4 percent compared with 27.3 percent for surgical replacement.

"We also performed multiple different subgroup analyses for one-year death rates and found the survival benefit of TAVR with CoreValve was consistent across all clinical subgroups we examined, regardless of thresholds," Adams said.

The 30-day observed death rates for TAVR and surgical valve replacement were much lower than the anticipated rate of 15 percent, Adams said, suggesting that the patient population may have had lower risks than intended. In addition to the STS score, frailty and other disabilities were considered in the evaluation of risk. Randomization ensured a robust trial nonetheless, he said, adding that this study confirmed that current risk assessment models, including expert physician reviews, overestimate contemporary surgical risks.

A potential limitation of the study is the higher dropout rate for patients

randomly assigned to surgery, as reported with previous TAVR trials. Forty patients assigned to surgery dropped out of the study before treatment, while only four assigned to the TAVR arm dropped out. The trial was designed with this anticipated attrition rate, and a sensitivity analysis confirmed that there were no significant differences in the risk profiles between patients who underwent the assigned surgical treatment and those who withdrew, Adams said.

"We are confident that the higher withdrawal rate in the surgical arm did not affect our findings," he said.

Strong results from the other arm of CoreValve's U.S. Pivotal Trial with patients at extreme risk for standard aortic valve-replacement surgery were reported in October and led to Food and Drug Administration approval for the device in this population.

Provided by American College of Cardiology