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Favorable one-year clinical outcomes for catheter-based aortic valve replacement with latest generation of device

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Penn Medicine has performed more than 1,200 Transcatheter Aortic Valve Replacements (TAVR) on patients with severe aortic stenosis. Today, at the Transcatheter Cardiac Therapeutics conference in San Francisco, Howard C. Herrmann, MD, the John Winthrop Bryfogle Professor of Cardiovascular Diseases and director of Penn Medicine's Interventional Cardiology Program in the Perelman School of Medicine at the University of Pennsylvania, will present promising findings from the PARTNER II Trial, which examined one-year clinical outcomes among high-risk or inoperable patients who received TAVR with the latest generation of balloon-expandable (SAPIEN 3) device.

Previous results from the PARTNER I trial demonstrated that high-risk and inoperable patients - patients who would not have been considered candidates for traditional open-heart surgery to replace their aortic valve - had a low rate of 30-day complications. The new findings show that patients who received the newest device also experienced a very low rate of one-year mortality. Between the 30-day and one-year assessments, the low rate of disabling stroke and other adverse cardiovascular events remained low and stable. The data also showed that the patients' symptom relief and the valves' performance held up over the course of the first year after undergoing the surgery.

"TAVR offers patients who are at high-risk for open-heart surgery an alternative treatment for their aortic stenosis, and a way to improve both

their survival and quality of life," Herrmann said. "This study shows that the new design features of this latest generation device, coupled with improvements in the surgical procedure, operator experience, and patient selection, can allow even high-risk patients to get the benefits of TAVR with strikingly low rates of one-year mortality and other complications."

The team, drawn from 10 centers across the United States, examined a group of 583 TAVR recipients, and evaluated the use of Transfemoral (TF) and Transapical/Transaortic (TA/TAo) access to assess one-year efficacy. The team tracked all-cause mortality, cardiovascular mortality, and disabling stroke in recipients, and compared high-risk and inoperable patient outcomes. At one year, 85 percent of patients were alive. Among patients whose valves were replaced via the transfemoral procedure, 87 percent were alive, and 89 percent of a subgroup of high-risk patients survived. The study also found that there was a low rate of disabling stokes at one year - striking less than three percent - with no difference between high-risk and inoperable patients or TF and TA/TAo procedures. Additional results concluded that paravalvular aortic regurgitation - a leak in the aortic valve following surgery - remained low, with under three percent exhibiting moderate regurgitation and 29 percent having mild regurgitation at one year. Importantly, there was no increased mortality observed among the patients with mild regurgitation as compared to those with mild or no leakage, and no patient in the group experienced severe leakage.

These results prove promising for high-risk and inoperable patients, as shown through a 50 percent reduction in mortality - in both patient groups - after one year, when compared to the first generation TAVR device study. This reduction comes primarily as a result of the new device design features along with improved patient selection, surgical procedure improvements, and additional operator experience. Herrmann added, "additional investigation of this device in comparison to conventional open-heart surgery for intermediate and low-risk patients

will be essential in supporting a broader use of TAVR. However, this data further supports the use of TAVR as the preferred method for treating aortic stenosis in high-risk and inoperable patients."

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