# Researchers find transcatheter aortic valve replacement better for patients with severe aortic stenosis

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Aortic stenosis (AS), the narrowing of the aortic valve opening which restricts blood flow to the aorta, afflicts nearly 1.5 million people in the United States, with approximately 500,000 of them suffering severe aortic stenosis. While open-heart surgery has historically been the recommended treatment for AS, some patients at high or extreme risk are not considered good candidates. Today, new data demonstrates that for patients at intermediate-risk for open-heart surgery, transcatheter aortic valve replacement (TAVR) with the latest generation of balloon-expandable device - SAPIEN 3 - is superior to surgery, resulting in better patient outcomes. This study, conducted by researchers in the Perelman School of Medicine at the University of Pennsylvania, in partnership with Edwards Lifesciences, the Cardiovascular Research Foundation, and 50 centers across the United States and Canada, was presented today at the American College of Cardiology 65th Annual Scientific Session in Chicago and simultaneously published online in *The Lancet*.

TAVR is a minimally invasive procedure which repairs the aortic valve without removing the old, damaged valve. In this case, the aortic valve is replaced with the SAPIEN 3, a device inserted into the heart to help the aortic valve open properly. The SAPIEN 3 device was recently approved by the Food and Drug Administration (FDA) for the treatment of high-risk patients.

Researchers enrolled 1,078 patients with severe, symptomatic aortic stenosis who were classified as being intermediate-risk for open-heart surgery. This risk classification is determined based on a patient's age, presence of other chronic disease, whether they have undergone previous surgeries, among other criteria. Using a pre-specified propensity-score analysis, one-year SAPIEN 3 outcomes were compared with one-year surgical outcomes from 944 intermediate-risk patients treated with surgery in the PARTNER II randomized trial - this study was presented yesterday at ACC Annual Scientific Session.

"For patients with severe, symptomatic aortic stenosis, a substantial obstruction of the aortic valve, surgery is the gold-standard treatment," said Howard C. Herrmann, MD, FACC, MSCAI, John W. Bryfogle Professor of Cardiovascular Medicine and Surgery, director of Penn Medicine's Interventional Cardiology Program, and co-author on the study. "However, these results prove that use of the SAPIEN 3 is more beneficial for intermediate-risk patients, who may otherwise experience surgical complications. Ultimately, TAVR with SAPIEN 3 can help alleviate severe, symptomatic AS with a less invasive alternative to open-heart surgery, which is especially important given that the age of most patients is over 75 years."

Data shows that patients who underwent TAVR instead of surgery have better one-year outcomes based on mortality and stroke.

"We have already evaluated the benefit of SAPIEN 3 for high-risk patients in a study that was published in the fall, and now we have data to support the advantage of using this device in intermediate-risk patients," said Wilson Y. Szeto, MD, an associate professor of Cardiovascular Surgery, chief of Cardiovascular Surgery at Penn Presbyterian Medical Center, and co-author on the study. "The next step will be to investigate whether TAVR with SAPIEN 3 is the best option for low-risk patients, which could result in a new treatment paradigm for all patients with aortic stenosis."

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