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Researchers find similar outcomes for patients with severe aortic stenosis who undergo transcatheter aortic valve replac

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Nearly 1.5 million Americans have aortic stenosis (AS), the narrowing of the aortic valve opening which restricts blood flow to the aorta. Historically, patients have been treated with open-heart surgery, although recent research has suggested that transcatheter aortic valve replacement (TAVR) may be a better, less invasive treatment option for some high-risk patients. In this first randomized clinical trial for intermediate-risk patients with severe, symptomatic AS, conducted by researchers in the Perelman School of Medicine at the University of Pennsylvania, in partnership with Edwards Lifesciences, the Cardiovascular Research Foundation, and 56 center across the United States and Canada, investigators found that TAVR with SAPIEN XT resulted in similar two-year clinical outcomes, as compared to surgical aortic valve replacement. The study - the PARTNER II Trial - was presented today at the American College of Cardiology 65th Annual Scientific Session in Chicago and simultaneously published online in The *New England Journal of Medicine*.

TAVR is a minimally invasive procedure which repairs the aortic valve without removing the old, damaged valve. The valve is replaced with the SAPIEN XT, a balloon-expandable device inserted into the heart to help the aortic valve open normally.

Researchers stratified 2,032 patients by site of access: transfemoral - entering through the groin - or transapical / transaortic - entering through

the chest. The patients were then randomly assigned to undergo either TAVR with the SAPIEN XT device or surgical aortic valve replacement. After their respective procedures, patients were followed for at least two years, including evaluation by a neurologist. The main goal of the study was to compare the effectiveness of TAVR with SAPIEN XT to surgical aortic valve replacement with respect to all-cause mortality or disabling stroke.

"In this study, TAVR and surgical valve replacement had similar mortality and stroke outcomes, which achieved the initial goal, but patients who underwent TAVR with SAPIEN XT experienced some added advantages," 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. "Having followed the participants for two years, we found that patients treated by TAVR with SAPIEN XT saw additional benefits terms of reducing severe bleeding, length of stay and presence of new atrial fibrillation."

All patients treated with the SAPEIN XT device achieved successful two-year outcomes, and patients specifically treated transfemorally had superior outcomes to surgery. Of the patients treated with SAPIEN XT, 19 percent experience all-cause mortality or disabling stroke at two years, as compared with 21 percent of those who had surgery. And for the 76 percent of SAPIEN XT patients treated via the transfemoral approach, the event rate was even less at 17 percent, compared to 20 percent with surgery.

"While the numbers differ only by about three percent in the TAVR group versus the surgery group, a reduction in mortality and disabling strokes of any amount is progress," 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 evaluate low-risk patients with severe, symptomatic aortic stenosis."

Provided by University of Pennsylvania School of Medicine