Encouraging early results for redesigned Sapien valve

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The new Sapien XT aortic valve showed a non-significantly lower rate of death and strokes at 30 days than the original model, and both valves demonstrated notably better short-term outcomes than seen with the Sapien system in PARTNER I, according to the first results from the PARTNER II study presented today at the American College of Cardiology's 62nd Annual Scientific Session.

PARTNER II is the first randomized clinical trial involving the Sapien XT valve and the only one that compares the new device to the original FDA-approved Sapien design. The redesigned Sapien XT has been commercially available for some time in most other parts of the world except the United States.

Three years ago the first PARTNER trial reported an almost doubled risk of stroke at 30 days for patients in the Sapien transcatheter system group compared with those who had standard open-heart surgery. After that period, the stroke risk leveled off for both groups. The new valve is part of a three-component system—a metal stent frame, a valve leaflet and a catheter—and each piece has been materially changed to make the device smaller and thinner. The frame, formerly stainless steel, is now a thinner cobalt chromium alloy and uses less metal overall, allowing the device to be compressed tighter.

"With the new device, we can treat patients who have smaller vessels with less injury and less trauma, and the valve positioning is more precise," said Martin B. Leon, MD, professor of medicine and director

of the Center for Interventional Vascular Therapy, Columbia University Medical Center, New York, and co-principal investigator of the PARTNER studies. "Any time you get below 20 French in catheter size, that's significant for patient safety."

PARTNER II's Cohort B compares the original and new Sapien systems in 560 patients with severe aortic stenosis who were very old, with a mean age more than 84 years, and very sick. More than 96 percent were classified with NYHA Class III (moderate) or Class IV (severe) heart failure, and 59 percent were assessed as clinically frail. All patients were deemed unsuitable for standard open-heart surgery.

This non-inferiority study was designed to show that the new Sapien XT is at least as safe and effective as the old device. At 30 days, all-cause deaths were 3.5 percent for Sapien XT and 5.1 percent for the original device.

"These are the lowest 30-day mortality results for transcatheter aortic valve replacement in any study using rigorous clinical trial methodology," Dr. Leon said. "For these inoperable patients, the sickest of the sick, they're surprisingly good."

Stroke rates at 30 days also were low in both groups, at 3.2 percent for Sapien XT and 3 percent for Sapien, and much lower than in PARTNER I.

The composite one-year endpoint is all-cause mortality, disabling stroke and repeated hospitalization for problems related to aortic stenosis. These data will be presented at the conference.

With the new device, the total procedural time was shorter, the frequency of vascular complications was lower and there were far fewer vascular perforations. In the Sapien group, 10 patients required a second

valve because of malfunction or mispositioning, compared with only three patients in the Sapien XT group.

"This device is more stable and doesn't move as much as the original device did," Dr. Leon said. "We didn't give up anything in performance to get this lower profile and its benefits."

The study's Cohort A will compare the new Sapien XT with open-heart surgery in intermediate-risk rather than high-risk patients.

Provided by American College of Cardiology