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Evidence supports wider use of transcatheter aortic valve replacement

Design advances and continuing clinical investigation are expanding the use of transcatheter aortic valve replacement (TAVR). Originally approved for aortic stenosis (AS) patients who were not considered candidates for open valve-replacement surgery, the percutaneously placed valve is now approved for use in patients who are at intermediate risk for open surgery. A new trial is currently collecting data comparing TAVR to surgical valve replacement in low-surgical-risk patients, potentially further expanding the criteria for the minimally invasive procedure.

Aortic stenosis is a condition where the aortic valve is damaged and narrowed. TAVR enables doctors to replace aortic valves without making an incision in the chest wall. Somewhat similar to placing a stent in an artery, TAVR delivers a fully collapsible bioprosthetic valve to the base of the aorta. This procedure is now more often being done percutaneously.

UCLA was among the first centers to offer TAVR as a treatment option for patients with inoperable and high surgical risk AS in 2012, and continues to remain at the forefront of its evolution.

The changing face of cardiac care at UCLA

Third-generation transcatheter aortic valve replacement (TAVR) continues to prove itself as an alternative to conventional surgery.

"The combination of new design features and procedural improvements to next generation TAVR valves has contributed to the current, strikingly low TAVR mortality rates," says William Suh, MD, associate clinical professor of interventional cardiology. "The delivery system has increased the proportion of valve replacements we are able to do transfemorally, which has enhanced our ability to perform the procedure using conscious sedation."

In addition to avoiding general anesthesia and intubation, conscious sedation allows the majority of TAVR patients to recover without the need for a stay in the intensive care unit following valve replacement, and to discharge home one or two days after the procedure.

"TAVR continues to transform the treatment of aortic stenosis worldwide. The clinical reality of a 'heart team' composed of a cardiologist and cardiac surgeon provides the patient with a robust consultation and opinion regarding the best procedure," says Richard J. Shemin, MD, Robert & Kelly Day Professor and Chief, Division of Cardiac Surgery.

Continued trials investigate expanded use of TAVR

The most common cause of aortic stenosis is age-related calcium deposits. While these deposits may never cause problems for some patients, the narrowing of the valve can lead to reduced blood flow and increased strain on the heart, increasing risk of chest pain, irregular heart rhythms (arrhythmias), cardiac arrest, heart failure and fainting episodes. In addition to a diminished quality of life, more than half of critical AS patients receiving only medical therapy do not survive two years from the onset of their symptoms.

The TAVR procedure is currently FDA-approved for patients who are at high and intermediate risk for a surgical approach. UCLA is currently an investigating site for the latest trial, which compares TAVR to surgical valve replacement among patients who are low surgical risks. The new study includes non-randomized registries for valve-in-valve use and for patients with bicuspid valve disease (which had been an exclusion criterion for all previous TAVR trials). Valve-in-valve replacement enables the surgeon to replace aortic valves where a previously placed bioprosthetic-tissue valve has broken down and the valve has failed with age.

Dramatic design improvements in third-generation heart valve

In June 2015, the FDA approved the third and latest replacement valve. Clinical outcomes based on a rigorous trial analysis of 583 high-risk AS patients showed steady improvement in TAVR technology, including significantly lower complications such as paravalvular leakage, stroke and mortality rates.

A key design adjustment over previous iterations was the addition of an outer skirt or cuff of fabric at the base of the valve to minimize leakage (paravalvular regurgitation) associated with increased mortality. The study found that the average rate of regurgitation at 30 days for the third–generation THV was reduced to just 3 percent compared to 14 percent for earlier devices.

Among other results, disabling stroke declined from 3 percent to 0.8 percent with the latest version and mortality rates fell from 6 percent to about 1 percent. Another major advantage of the new device is a smaller delivery system through the femoral artery, leading to less vascular injury.

The only TAVR center in the region to offer conscious sedation

The UCLA team of nationally recognized TAVR specialists includes interventional cardiologists, cardiothoracic surgeons, anesthesiologists, echocardiographers and heart-lung machine technologists, all working together to address the needs of each patient. In most cases, patients are evaluated at the UCLA Cardiovascular Center within one week of referral by the cardiologist and cardiac surgeon to determine suitability of a TAVR procedure.

UCLA currently has the only hospital in Los Angeles County with the expertise and resources to offer qualified individuals the option to be lightly sedated but fully awake during the procedure, eliminating the need for general anesthesia and reducing hospital recovery time.

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For more information about the TAVR procedure at UCLA and to view a video, go to **heart.ucla.edu/interventional-cardiology/tavr**