U.S. Food and Drug Administration

News & Events

FDA NEWS RELEASE

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FDA approves first artificial aortic heart valve placed without open-heart surgery

The U.S. Food and Drug Administration today approved the first artificial heart valve that can replace an aortic heart valve damaged by senile aortic valve stenosis without open-heart surgery.

Senile aortic valve stenosis is a progressive, age-related disease caused by calcium deposits on the aortic valve that cause the valve to narrow. As the heart works harder to pump enough blood through the smaller valve opening, the heart eventually weakens, which can lead to problems such as fainting, chest pain, heart failure, irregular heart rhythms (arrhythmias), or cardiac arrest.

Once symptoms of senile aortic stenosis occur, more than half of patients die within two years. To restore normal blood flow, patients with severe aortic valve stenosis need open-heart surgery to replace the diseased valve. However, the procedure is too risky for some patients.

"Surgery to replace the aortic valve is an effective treatment for severe senile aortic valve stenosis. The Sapien Transcatheter Heart Valve (THV) is an example of an innovative new device that will provide some people with this condition who can't undergo open heart surgery with the option of valve replacement," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "The agency remains committed to working with companies who are developing breakthrough treatments that will have a significant impact on patient care in the U.S.

The Sapien THV is made of cow tissue and polyester supported with a stainless steel mesh frame. To replace the diseased valve, the Sapien THV is compressed into the end of a long, thin, tube-like device called a delivery catheter. The delivery catheter, which is slightly wider than a pencil, and the Sapien THV are inserted into the femoral artery through a small cut in the leg and threaded to the site of the diseased valve. The heart valve is then released from the delivery catheter and expanded with a balloon and is immediately functional.

The FDA's approval of the Sapien THV is based on a study in 365 patients who were not eligible for open-heart surgery. Half of the patients received the Sapien valve. The other study patients received another treatment that did not require open-heart surgery. One alternative procedure involved enlarging the aortic valve opening by stretching it with a balloon (balloon valvuloplasty).

Patients receiving the Sapien valve experienced two and a half times more strokes and eight times as many vascular and bleeding complications than patients who did not receive the implant; however, they were more likely to survive one year after surgery. After a year, 69 percent of the Sapien patients were alive compared with 50 percent of those who received an alternative treatment.

Edwards Lifescience, the manufacturer of the Sapien THV, will continue to evaluate the outcomes with the Sapien THV through a national Transcatheter Valve Therapy (TVT) registry. The Society of Thoracic Surgeons and the American College of Cardiology have been working with the FDA and the Centers for Medicare and Medicaid Services to facilitate the creation of the national TVT registry that will serve as a platform for continued evaluation of post market experience with this and future transcatheter devices and procedures for the treatment of aortic stenosis.

The most common serious and potentially life-threatening side effects in patients receiving the Sapien valve and the procedure to implant the valve include death, stroke, perforation of the blood vessels, ventricle or valvular structures, damage to the conduction system in the heart, significant bleeding, and leaks around the new valve.

The Sapien THV is approved for patients who are not eligible for open-heart surgery for replacement of their aortic valve and have a calcified aortic annulus (calcium build-up in the fibrous ring of the aortic heart valve). The product label advises that a heart surgeon should be involved in determining if the Sapien THV is an appropriate treatment for the patient.

It is not approved for patients who can be treated by open-heart surgery. Patients who have congenital heart valve anomalies, have masses or an infection in their hearts, or cannot tolerate anticoagulation/antiplatelet therapy should not receive the Sapien THV.

Edwards Lifescience is located in Irvine, Calif.
For more information:
FDA: Medical Devices [1]

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