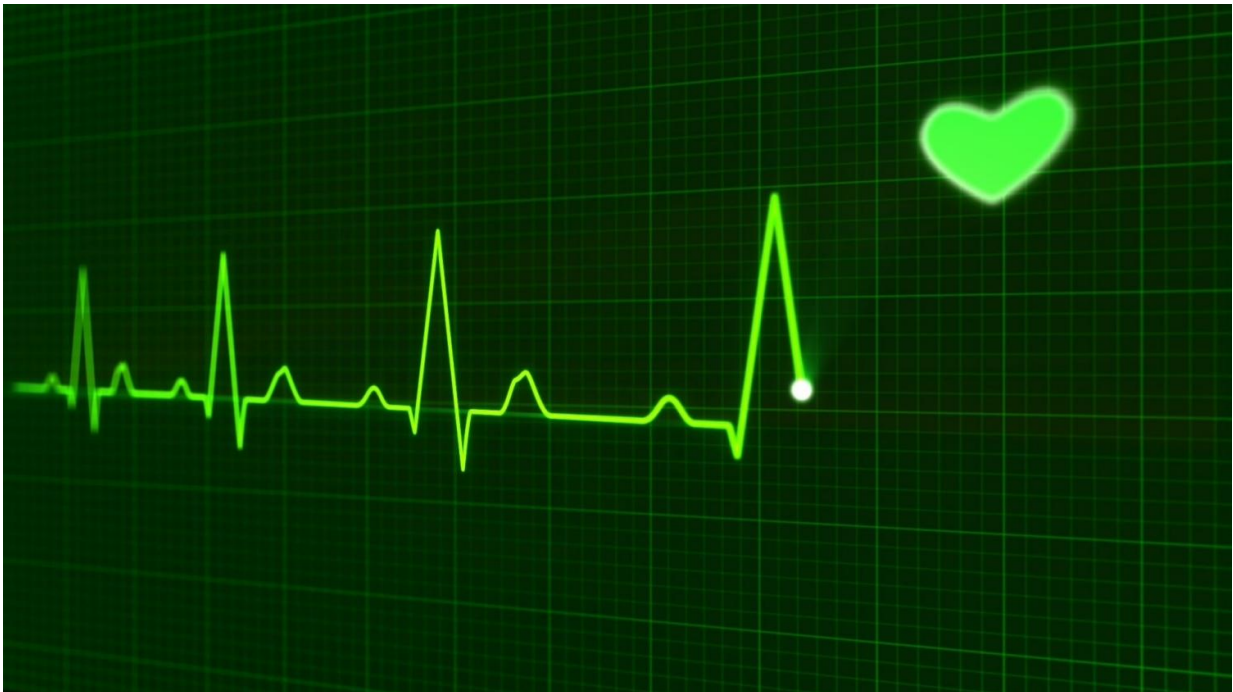


Mechanical heart valve often the safest choice, study says

November 8 2017



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Mechanical heart valves may be safer in certain cases than valves made of animal tissue and should be used more in heart-valve replacements, especially in younger patients, according to a study by researchers at the Stanford University School of Medicine.

The study also found that unlike what's recommended in the national

guidelines, which say patients ages 50 to 70 undergoing aortic or mitral valve replacement should be given a choice of either a mechanical or biological valve, the best choice in fact can hinge on whether the aortic or mitral valve is being replaced.

The study shows that for patients undergoing mitral valve replacement, a mechanical valve is actually beneficial until the age of 70. On the other hand, for patients undergoing aortic valve replacement, the benefit of implanting mechanical valves ceased after the age of 55.

"This has potential to significantly impact the current national practice guidelines," said Joseph Woo, MD, professor and chair of cardiothoracic [surgery](#) at Stanford, who routinely performs these surgeries. "While our preference is always to repair heart valves whenever possible, there are certain disease processes which necessitate valve replacement. For these patients, given the study's new and unexpected findings, I am already pondering, 'How am I going to counsel my patients today?' The advice may not be the same as the current national guideline recommendations."

The study will be published Nov. 8 in *The New England Journal of Medicine*. Woo is the senior author. Postdoctoral scholar Andrew Goldstone, MD, PhD, is the lead author.

Most patients who need open-heart surgery to remove a diseased heart valve face complicated conversations with their heart surgeons about whether to use a natural-tissue or mechanical valve as a replacement.

Mechanical valves can last a lifetime, but they come with increased risks of blood clotting and bleeding and a lifetime of having to take the blood-thinning medication warfarin. Biological valves, which are most often made from pig or cow tissue, don't increase the risk of bleeding or clotting, but they wear out within about 10 to 15 years, making a second surgery likely.

'A perplexing question'

"This is a perplexing question and comes up for me every single day with patients," said Woo, who holds the Norman E. Shumway Professorship. The decision has been made difficult by the lack of sufficient scientific evidence to back up either choice, he said. Instead, it becomes something of an educated-guessing game based on the age of a patient, comorbidities, a patient's personal preferences and the somewhat vague national guidelines published by the American Heart Association and American College of Cardiology. For those younger than 50, a mechanical valve is currently recommended, and for those older than 70, a biologic tissue valve is recommended, Woo said.

However, the associations' guidelines don't distinguish between whether the mitral or aortic valve is being replaced.

"If you think about this just in terms of age, the older you are, the less likely that you will outlive the durability of a biological valve," Woo said. He added that surgeons have noted in recent years a trend toward younger patients choosing biological valves, primarily because they don't want to deal with a lifetime of taking blood thinners and with the accompanying dietary restrictions and routine blood testing necessitated by a mechanical valve.

The American Heart Association estimates that 5 million Americans suffer from heart-valve disease, which forces the heart to work harder to pump blood and can lead to heart failure and sudden death. The disease can be present at birth or result from infections, heart attacks or other heart conditions.

When a valve becomes so diseased that it impedes the delivery of blood to the body, open-heart surgery to replace the valve with a new one generally is recommended. Each year, more than 50,000 people in the

United States undergo either aortic- or mitral-valve replacement surgery, according to the study.

To compare the long-term risks and benefits of mechanical versus biological [heart valves](#), researchers examined rates of mortality, stroke, bleeding and reoperation in patients who underwent heart-valve surgery at 142 hospitals in California between 1996 and 2013. Patient records were obtained from the California Office of Statewide Health Planning and Development databases.

Researchers examined the records of 9,942 patients who underwent aortic-valve replacement and 15,503 patients who underwent mitral-valve replacement during the study period.

"Our research likely contains the largest number of patients ever studied to examine this issue," Woo said.

A stark difference

Results showed a stark difference in health benefits depending on which valve was being replaced, Woo said. The long-term mortality benefit associated with a mechanical valve compared with a biological valve persisted until age 70 in patients undergoing mitral-valve replacement, the study found. For those undergoing [aortic-valve replacement](#), this benefit persisted only until age 55.

"This study will definitely change the information that I give my patients," said Jennifer Lawton, MD, professor of surgery and chief of the Johns Hopkins University Division of Cardiac Surgery, who was not involved with the study. Lawton, like Woo, faces the same daily discussion with her patients about which valve to choose. "The benefit of this study is that it looks at so many patients over a period of time," she said. "Up until now, there have only been small studies on which the

guidelines are based."

The current national guidelines are based on data from studies that are not only small, but which examined the use of now-obsolete valves that were implanted more than 30 years ago, the study said.

"Over the last 15 or 20 years around the world, there has been a dramatic shift in the increased use of bioprosthetic valves," said Michael Argenziano, MD, professor of surgery and chief of adult cardiac surgery at Columbia University. "This is the first paper to provide solid evidence that maybe we have been moving too quickly away from the [mechanical valve](#)." Argenziano was not involved in the study.

Sharing the results of this study with patients is particularly urgent right now because of this growing trend toward younger patients choosing biological valves, Woo said.

"People just don't want to take blood thinners," Woo said, adding that patients are also hoping that experimental transcatheter technology, which could allow [valve replacement](#) without the need for open heart surgery, will be available for them in 10 or 15 years when they would potentially need another surgery.

Lawton agreed that she's seen a similar trend and believes it's probably occurring across the United States and the world.

"People don't want to change their lifestyles, in particular women who want to have children and don't want to take blood thinners," she said.

This new study should give both [patients](#) and their surgeons valuable new information, Woo said.

"For most heart surgeons who have to face this conversation every single

day, this choice is very much on our minds," Woo said. "For many [heart](#) surgeons throughout the country and beyond, this study could have a major impact."

Provided by Stanford University Medical Center

Citation: Mechanical heart valve often the safest choice, study says (2017, November 8)
retrieved 24 April 2024 from
<https://medicalxpress.com/news/2017-11-mechanical-heart-valve-safest-choice.html>

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