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Newer heart valve procedure gets boost

Medtronic, Edwards Lifesciences touted data showing outcomes for their systems.

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The case for wider use of minimally invasive heart-valve replacement procedures received a significant boost over the weekend from a pair of studies that found the new valves work just as well or better than traditional aortic-replacement valves in the aortic position. They had lower rates of death and stroke, but Medtronic's device had a higher rate of pacemaker implants afterward.

At an industry conference in New Orleans on Sunday, Minnesota's Medtronic and California's Edwards Lifesciences presented the results of two long-awaited randomized controlled trials of a therapy called TAVR, or "transcatheter aortic valve replacement." Patients in the trials were at low risk of dying from traditional surgery, but they got TAVR anyway.

"TAVR [transcatheter aortic valve replacement] is now starting to look like the preferred strategy."

Dr. Michael Reardon

Proponents and skeptics alike predicted the studies would increase the use of the increasingly popular therapy for aortic stenosis.

"At the end of one year, for the TAVR patients you were more likely to be alive without a disabling stroke and without a heart failure hospitalization," said Dr. Michael Reardon, principal investigator for Medtronic's low-risk TAVR trial. "If you add that to the early superior safety of TAVR, the earlier recovery, the less time in the hospital, TAVR is now starting to look like the preferred strategy, and not just an alternative therapy, in this patient population."

After two years, 5.3 percent of the Medtronic TAVR patients and 6.7 percent of the traditional surgical valve patients had either died or had a disabling stroke — outcomes so close that Medtronic's TAVR valve was judged "non-inferior" to the surgical alternative, the study data show. However 19.4 percent of the TAVR patients ended up with an implanted pacemaker, because of how the valve presses against the heart tissue, while 6.7 percent of the traditional surgery patients received a pacemaker. More than 1,400 people were randomized to one of the two options in that study.

Looking at the Edwards study, at one year 8.5 percent of the TAVR patients died, had a stroke or were rehospitalized, compared with 15.1 percent in the surgery group — a difference wide enough to call TAVR "superior" in the one-year time frame, the study said. Pacemaker rates were the same in both groups, but the percentage of patients who got an electrical problem

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◂ TAVR from D1

in the heart called left-bundle branch block was 23.7 percent in the Edwards TAVR group, and 8 percent in the surgical group.

With both TAVR valves, hospital times and recovery times were shorter than the traditional surgeries because the valves are inserted via a small puncture elsewhere in the body and threaded into the heart using a thin catheter.

Dr. Gurpreet Sandhu, chairman of interventional cardiology at Mayo Clinic in Rochester, predicted that TAVR volumes will probably double in the next few years.

"Basically, with both of these FDA-approved valves, I think we saw excellent results that seem to be as good as open-heart surgery," said Sandhu, who was not involved in either study but has reported Medtronic research funding in the past.

Data from the two company-sponsored trials presented Sunday at the annual American College of Cardiology meeting will be sent to the U.S. Food and Drug Administration, which will decide whether to approve the TAVR valves for use in patients at low risk of problems from traditional open-chest surgery for aortic stenosis. The valves are already approved for higher-risk patients.

Aortic stenosis is a serious condition in which the aortic valve becomes narrowed, preventing some blood from leaving the heart. Doctors have been using open-chest surgery to implant mechanical valves with solid carbon leaflets for more than 50 years, though durable, mechanical valves require lifetime use of anti-coagulation drugs.

Other valves use animal tissue instead of solid leaflets to regulate blood flow through the aortic opening. Traditional "bioprosthetic" tissue valves, also implanted with open-chest surgery, can wear out faster but don't require blood thinners. TAVR valves are bioprosthetic valves that can be folded up and later unfurled inside the heart.

Today, Medtronic's Evolut and Edwards' Sapien TAVR valves are approved only in patients who face a high or intermediate risk of dying from traditional surgery. Many doctors came away from Sunday's presentations enthusiastic about the devices' performance in low-risk patients. Doctors presenting TAVR data at cardiology conference on Sunday received standing ovations.

"In terms of how we think about TAVR now, things will change," said Dr. Paul Sorajja, a Minneapolis interventional cardiologist with Allina Health who was an investigator in the Medtronic study. "It's not going to be so much about determining whether [patients with aortic stenosis] are surgical candidates. We're really just determining whether they are a TAVR candidate."

Other doctors were concerned that TAVR adoption could spread quickly without long-term data, especially for low-risk patients who already have a safe procedure in traditional implantation.

Dr. Rita Redberg, a cardiologist with UCSF Health in California and editor of JAMA Internal Medicine, said she's concerned that patients with no symptoms could get TAVR valves. In the past, those patients may have been more likely to delay surgery until they felt symptoms.

"I won't be changing my practice," Redberg said. "I think it's hard to justify doing this serious procedure on healthy, low-risk asymptomatic people without data that they're better off with it. And we don't have that."

TAVR valves cost more, but the price is offset by less hospital time. A 2017 paper in the Journal of the American College of Cardiology found that TAVR valves and supplies averaged $26,000, compared with $15,000 for surgical valve replacement. However, TAVR procedures had $25,500 in hospital and lab charges, vs. $34,500 for surgical valves.

Investors sent shares of Edwards Lifesciences up 6 percent, to $190.89 Monday. Medtronic shares were off 2 percent, to $91.89.

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