

# TAVR found non-inferior to surgery in broad patient population

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Patients who underwent transcatheter aortic valve replacement (TAVR) did not have a higher rate of death at one year compared with those who had their heart valve replaced via open-heart surgery, according to

research presented at the American College of Cardiology's Annual Scientific Session Together with World Congress of Cardiology (ACC.20/WCC).

The trial compared approaches to replacing the [aortic valve](#) in patients with severe aortic stenosis, a condition in which the valve becomes narrowed, impeding the proper flow of blood. Untreated, aortic stenosis causes breathlessness, fatigue and other symptoms and increases the risk of other heart problems. Traditionally, surgeons have replaced the valve via open-heart [surgery](#), but the less invasive TAVR approach, in which clinicians thread the new valve through a small tube inserted into an artery in the groin, underarm or chest into the aorta and up to the heart, has rapidly become more common in recent years.

Previous clinical trials have found TAVR to be non-inferior or superior to open-heart surgery for various patient groups, but most trials have been limited to medical centers that perform a high volume of procedures or focus on the use of specific types of replacement valves. The new trial involved a broad group of patients who were treated at every medical center that performs TAVR across the United Kingdom.

"The importance of this trial is that it confirms the effectiveness of the TAVR strategy in a real-world setting," said William D. Toff, MD, professor of cardiology at the University of Leicester and the study's lead author. "It wasn't only conducted at the best centers, and it wasn't limited to a particular valve under ideal conditions. This was TAVR as it is in the real world compared with surgery as it is in the real world."

The trial enrolled 913 patients referred for treatment of severe aortic stenosis at 34 U.K. sites from 2014-2018. Half were randomly assigned to receive TAVR and half underwent open-heart surgery. Enrollment was limited to participants age 70 years or older (with additional risk factors) or age 80 years or older (with or without additional risk factors).

Overall, participants were at intermediate to low risk from surgery, with a median Society of Thoracic Surgeons risk score of 2.6% (a score below 3% is considered low risk). However, researchers did not specify a particular risk score cut-off for enrollment. This allowed the trial to evolve along with changes in guidelines and practice regarding TAVR over the course of the study and to reflect physicians' nuanced, real-world approach to considering risk in decision-making rather than taking a formulaic approach, Toff said.

At one year, the rate of death from any cause was 4.6% among patients undergoing TAVR and 6.6% among those undergoing [open-heart surgery](#), a difference that met the trial's pre-specified threshold for non-inferiority of TAVR. Rates of death from cardiovascular disease, stroke and a composite of those two outcomes were similar between the two groups.

Patients who received TAVR had a significantly higher rate of vascular complications, which occurred in 4.8% of TAVR patients and 1.3% of those receiving surgery. TAVR patients were also more likely to have a pacemaker implanted, which was necessary in 12.2% of TAVR patients and 6.6% of those receiving surgery. In addition, patients who underwent TAVR had a higher rate of aortic regurgitation (blood leaking through the [valve](#)), a finding that might, in some cases, adversely affect long-term outcomes. Mild aortic regurgitation occurred at one year in 38.3% of patients undergoing TAVR and 11.7% of patients undergoing surgery, while moderate regurgitation occurred in 2.3% of TAVR patients and 0.6% of surgery patients.

On the other hand, patients undergoing TAVR had a significantly lower rate of major bleeding complications, which occurred in 6.3% of TAVR patients and 17.1% of those undergoing surgery. TAVR was also associated with a shorter hospital stay, fewer days in intensive care, and better functional capacity and quality of life measures at six weeks after

the procedure. Functional capacity and quality of life were similar between the two groups at one year, however.

Toff said that the results reflect only a relatively short follow-up period, and that longer-term outcomes could reveal important differences. The researchers plan to continue to track outcomes for a minimum of five years.

"I think it's important that we take a measured approach and individualize the decision-making for these patients, factoring in the patient's preference and attitude to risk," Toff said. "The results from our trial and others are encouraging, but [patients](#) need to be fully informed and know that the long-term durability of the TAVR valves and the long-term implications of the increased risk of aortic regurgitation are still uncertain."

Provided by American College of Cardiology

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