

Low-risk patients may benefit from less invasive transcatheter valve replacement

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A new study by a team of cardiologists at Beth Israel Deaconess Medical Center (BIDMC) led by senior and corresponding author Jeffrey Popma, MD, suggests that a minimally invasive procedure currently reserved for patients too frail to undergo surgery may in fact be a safe and effective alternative for healthier patients. The findings were presented this weekend at the American College of Cardiology conference in New Orleans and concurrently published in *The New England Journal of Medicine*.

Popma and colleagues compared outcomes of surgical aortic valve replacement, in which the chest and heart are opened in the operating room, versus the less invasive transcatheter aortic valve replacement (TAVR), performed via catheters placed in the legs. More than 1,400 patients were randomized in the study to treatment with TAVR or surgical aortic valve replacement. All patients—65 percent male and with a mean age of 74—were deemed at low surgical risk, with physicians predicting they had no more than a three percent risk of death within 30 days with [surgery](#).

Thirty days after the procedure, patients who had undergone TAVR had a lower incidence of disabling stroke, bleeding complications, [acute kidney injury](#) and atrial fibrillation but a slightly higher incidence of moderate aortic regurgitation and more pacemaker need compared with patients who had undergone surgery. At 12 months, patients treated with TAVR had better valve function, with lower aortic-valve gradients and larger valve areas than those treated with surgery. After two years, rates

of death from all causes or disabling stroke were not different in patients treated with TAVR (5.3%) versus surgery (6.7%), although fewer patients treated with TAVR suffered a disabling stroke within 24 months than did patients treated with surgery.

"Given the low mortality and stroke incidence with aortic-valve surgery in relatively young, healthy patients, of TAVR at low surgical risk requires compelling demonstration of safety and effectiveness," said Popma, Director of Interventional Cardiology Clinical Services at BIDMC and Professor of Medicine at Harvard Medical School. "Further research is needed, but our study provides strong evidence that TAVR is a safe and effective therapy in patients at low risk for surgical [aortic valve replacement](#) 24 months after the procedure."

"Our surgeons performed aortic valve surgery with the highest quality, but even with excellent surgery, TAVR performed slightly better in a number of important endpoints that are relevant to patients, such as disabling stroke," added Popma. "What this means for our patients is that they will be able to make an informed choice about TAVR or surgery that will match their preferences for recovery, long-term valve durability and quality of life. I believe many patients will choose a less invasive approach."

The authors employed a novel Bayesian analytic method that allowed prediction of events rates in all 1400 patients based on the findings of 850 patients who had reached 12 months of follow-up, similar to prior studies from this study group in intermediate risk patients for surgery. As such, additional conclusions regarding the advantages and disadvantages of TAVR as compared with surgery await long-term clinical and echocardiographic follow-up as all patients reach 24 months after procedure.

"These results, coupled with the results from the balloon-expandable

randomized study reported at the same meeting, are truly transformative for our patients," said Roger Laham, MD, co-investigator for the study and Director, Structural Heart Center at BIDMC.

"Beth Israel Deaconess Medical Center has been fortunate to be a participant in these landmarks studies," said Robert Gerszten, MD, Chief of Cardiovascular Medicine BIDMC. "We look forward to following our [patients](#) treated in the study for the next decade to ensure the long-term durability of this therapy.

Provided by Beth Israel Deaconess Medical Center

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