Study examines use, outcomes of valve replacement procedure performed for off-label indications

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Approximately 1 in 10 transcatheter aortic valve replacement (TAVR) procedures in the U.S. were for an off-label indication, with similar 1-year mortality rates compared to on-label use, suggesting that TAVR may be a possible procedure option for certain patients requiring a heart valve replacement, according to a study published by *JAMA Cardiology*.

Transcatheter aortic valve replacement was approved by the U.S. Food and Drug Administration for severe aortic stenosis (narrowing of an artery) in patients who cannot undergo surgery and for patients at high operative risk.

Transcatheter aortic valve replacement is not currently recommended owing to limited proof of efficacy for a number of indications, including low surgical risk for conventional surgical aortic valve replacement (AVR) and moderate aortic stenosis; its use in such patients would be considered off-label. Use of TAVR for off-label indications has not been previously reported.

The authors note that off-label use implies that a therapy has not been studied in certain populations or for certain indications. It does not necessarily imply that therapy is inappropriate or ineffective for these patients.

Ravi S. Hira, M.D., of the University of Washington, Seattle, and colleagues examined patterns and adverse outcomes of off-label use of TAVR in U.S. clinical practice. The study included 23,847 patients from 328 sites performing TAVR between November 2011 and September 2014. Off-label TAVR was defined as TAVR in patients with the following conditions: known bicuspid valve, moderate aortic stenosis, severe mitral regurgitation, severe aortic regurgitation, or subaortic stenosis. Data were linked with the Centers for Medicare & Medicaid Services for 15,397 patients to evaluate 30-day and 1-year outcomes.

Among the patients in the study, off-label TAVR was used in 9.5 percent. Adjusted 30-day mortality was higher in the off-label group, while adjusted 1-year mortality was similar in the two groups. The median rate of off-label TAVR use per hospital was 6.8 percent.

"These results reinforce the continued need for additional research on the safety and efficacy of TAVR in specific patient cohorts with off-label indications for whom surgical AVR would be considered high risk or a prohibitive risk," the authors write.

More information: *JAMA Cardiology* (2017). jamanetwork.com/journals/jamac … jamacardio.2017.1685

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