

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.

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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/jamacardio.2017.1685](https://jamanetwork.com/journals/jamacardio/article/2017.1685)

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