

Study finds lower death rates for TAVR centers that do more procedures

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Hospitals that perform the highest volume of transcatheter-aortic valve replacement (TAVR) procedures have significantly lower mortality rates than centers that do fewer of the minimally invasive surgeries, according to an analysis by a collaboration that included the Duke Clinical Research Institute.

The finding, published April 3 in the *New England Journal of Medicine*, comes as the Centers for Medicare & Medicaid Services is reconsidering the procedure's coverage parameters, which established a center's volume as a key criterion for reimbursement.

Approved in 2011, TAVR is largely performed on [older patients](#) insured by Medicare, and has grown into a multi-billion-dollar annual industry. As the number of procedures has escalated and the technique and devices have evolved, questions arose over the necessity of volume standards for CMS coverage.

"What we found is that there is still a very real relationship with annual volume and 30-day mortality at the hospital level, even taking into account the new devices and the learning curve that new centers face in the first 12 months of initiating a program," said lead author and Duke cardiologist Sreekanth Vemulapalli, M.D.

"TAVR is different from most other cardiac procedures—it's not a single-person effort," Vemulapalli said. The procedure involves putting a replacement valve over a damaged [aortic valve](#) using a catheter rather than open-chest surgery, similar to the way a stent is placed in coronary arteries. "Patients are evaluated by a surgeon and an interventional cardiologist, and there is usually also a cardiac imaging specialist involved in the procedure. That team approach is very important, which is why we looked at the data from a hospital level."

Even so, the authors said, the relationship between higher TAVR volumes and lower mortality was also evident at the individual proceduralist level, suggesting that repeated practice does improve outcomes.

Vemulapalli and colleagues launched their analysis last summer after CMS announced it would reevaluate coverage criteria. Using a database

called the Transcatheter Valve Registry—which includes all of the commercial procedures in the United States, including those covered by Medicare—the researchers focused on volumes and outcomes from 2015-2017.

This timeframe rooted out earlier procedures that used outdated techniques and devices. The researchers also removed a hospital's first 12 months of cases to account for the learning curve. More than 500 hospitals were included and segmented into four groups based on volume, from lowest to highest.

Among nearly 100,000 transfemoral TAVR cases included in the analysis, the researchers found that hospitals in the group with the lowest volume had the highest 30-day mortality rate, at 3.19 percent, compared to hospitals in the group with highest volumes at 2.66 percent. This represents a relative reduction in patient mortality of 19.45 percent between the lowest- and highest-volume centers.

"This was the most comprehensive analysis of the outcomes of more than 100,000 people recently receiving TAVR in the U.S.," said John Carroll, M.D., professor of medicine at the University of Colorado School of Medicine and director of Interventional Cardiology at the UCHealth University of Colorado Hospital.

"The results definitively reaffirm an inverse relationship between the volume of procedures and the risk of death following the procedure," added Carroll, who is also the vice-chair of the STS-ACC TVT Registry Steering Committee. "The study's conclusive data should be incorporated by CMS in their final coverage policy to provide Americans with the best results from this transformative non-surgical therapy for the increasingly common condition of aortic stenosis, one of the most serious valve disease problems."

"These findings suggest a clear relationship between the volume of TAVR procedures and death at 30 days, both at the [hospital](#) level and at the individual operator level, and should be factored into the CMS revised National Coverage Determination related to TAVR until a validated quality outcome metric can be established," said co-author Michael Mack, M.D. "This relationship held true even after eliminating the first 12 months, meaning this is not just a 'learning curve.'"

Provided by Duke University Medical Center

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