

# First outcomes report from novel heart surgery registry shows excellent results for TAVR

November 30 2015

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Four years after its approval in the United States, transcatheter aortic valve replacement (TAVR) continues to evolve and demonstrate positive outcomes for patients with aortic stenosis, a common heart problem, according to a report published online by *The Annals of Thoracic Surgery* and the *Journal of the American College of Cardiology*.

Shortly after the Food and Drug Administration (FDA) approved the first heart valve for TAVR, the US Centers for Medicare & Medicaid Services (CMS) required all hospitals performing TAVR to capture clinical information in The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry) as a requirement for Medicare coverage. With collaboration from the FDA, CMS, the National Institutes of Health, and Duke Clinical Research Institute, the development and deployment of the STS/ACC TVT Registry represented the first time that such a diverse group came together to support the safe introduction and rational dispersion of a new medical device in the US.

In the report, David R. Holmes Jr., MD, from Mayo Clinic in Rochester, Minn., Frederick L. Grover, MD, from University of Colorado in Denver, and colleagues provided an overview of trends and analyzed outcomes of [patients](#) having TAVR procedures. The report also described the future of the TVT Registry.

"The most important takeaway is the fact that the TAVR procedure continues to change since its initial approval by the FDA in 2011," said Dr. Holmes. "Patients undergoing TAVR remain primarily elderly and high-risk for surgical replacement, but the predicted risk of mortality has declined over the course of time. This is the result of changes in regulatory instructions for use and approval of alternative access points."

The report included information on 26,414 TAVR procedures performed from January 1, 2012, through December 31, 2014, and recorded in the TVT Registry. The researchers compared outcomes in patients who underwent TAVR in 2012-2013 with the outcomes of patients who underwent the procedure in 2014. When TAVR was first approved, it required cardiothoracic surgeons and cardiologists to use transfemoral access (via the groin), but later expanded to include transapical (via the heart muscle), transaortic (via the aorta), and transcarotid (via the right common carotid artery) access.

The researchers found that TAVR patients in 2012-2013 and 2014 were elderly (average age 82 years), had multiple health conditions, were often frail, and had poor self-reported health status.

Results following the procedures also showed that risk for mortality, myocardial infarction (heart attack), kidney injury, and neurologic complications were low and appeared to be clinically consistent in both groups. The most common complications were vascular and bleeding requiring transfusion, but vascular complications decreased between 2012-2013 and 2014 (5.6% vs. 4.2%) and site-reported stroke rates remained stable at 2.2%.

"For patients, particularly those who are frail or elderly and have multiple health conditions, the outcomes reported thus far should provide reassurance that TAVR is safe and effective for the relief of symptoms in the short term," said Dr. Grover. "This patient population is

more often concerned with quality of life than long-term results, and our report shows that TAVR is a good option for them."

In addition, the researchers found that more heart teams are now using moderate sedation instead of general anesthesia, which allows for quicker recovery after surgery and shorter procedure durations. It also has the potential to reduce the patient's length of stay in the hospital, which can reduce overall hospital costs.

## **Importance for Patients**

As less invasive procedures become more available to patients, the TVT Registry will continue to play an important role in tracking both short- and long-term outcomes, as well as providing surveillance of medical devices once they are approved by the FDA.

"This Registry presents an incredible opportunity for physicians and their heart teams to be part of a novel post-market surveillance process, enabling STS and ACC to work very closely with regulatory agencies and industry," said Dr. Grover. "We believe that our work will help the FDA to approve important life-saving devices earlier, knowing that our Registry will be used to carefully monitor patients following device implantation."

## **Device Tracking Ability**

In addition to tracking patient outcomes, this first report from the TVT Registry also allowed researchers to track trends in device utilization over the course of the study period. "For example, one important finding we noticed in this report was that TAVR is currently underutilized in black patients (less than 5% of TAVR patients were black)," said Dr. Holmes. "Information like this would have been unknown to us before,

but because the Registry data were published, we know about the issue and can more easily address it in clinical practice."

## Future of the Registry

In an accompanying editorial, Michael J. Reardon, MD and Neal S. Kleiman, MD, from Houston Methodist DeBakey Heart & Vascular Center in Houston, discussed the impact that the TVT Registry has had to date and where they see it heading in the future. "The STS/ACC TVT Registry represents an unprecedented collaboration between the national [cardiology](#) and cardiothoracic surgery societies," said Dr. Reardon. "This multidisciplinary approach has shown tremendous benefit in other areas, such as oncology. I firmly believe that this 'team' approach will allow patients to benefit greatly from the best of both specialties."

He added that as TAVR enters the mainstream of clinical practice, the Registry will need to embrace new challenges and provide new opportunities, "Namely, the Registry will become more useful in showing the relationships between surgeon experience, institutional volume, and the likelihood of achieving favorable patient outcomes."

Provided by American College of Cardiology

Citation: First outcomes report from novel heart surgery registry shows excellent results for TAVR (2015, November 30) retrieved 5 May 2024 from <https://medicalxpress.com/news/2015-11-outcomes-heart-surgery-registry-excellent.html>

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