



The Society of Thoracic Surgeons
633 N. St. Clair, Suite 2320
Chicago, IL 60611
www.sts.org

News

STS Media Contact:

Cassie McNulty
312-202-5865

cmcnulty@sts.org

Embargoed for Monday, November 30, at 2:00 p.m. ET

First Outcomes Report from Novel Heart Surgery Registry Shows Excellent Results for Evolving TAVR Procedure

Report sets benchmark for TAVR, sets tone for registry's future

ACC Media Contact:

Katie Glenn
202-375-6472

kglenn@acc.org

Chicago – 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 transcatheter (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.”

###

Note: As of November 2015, the STS/ACC TVT Registry had more than 400 participants in 49 states, the District of Columbia, and Puerto Rico. A current list of STS/ACC TVT Registry participating hospitals can be found at <https://www.ncdr.com/TVT/Private/Resources/ParticipantDirectory.aspx>.

About the American College of Cardiology

The American College of Cardiology is a 49,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. For more information, visit www.acc.org.

About The Society of Thoracic Surgeons

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,100 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society’s mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy. The world-renowned STS National Database was launched in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. *The Annals of Thoracic Surgery* is the official journal of STS and the Southern Thoracic Surgical Association. It has a 5-year impact factor of 4.104, the highest of any cardiothoracic surgery journal worldwide. For more information, visit www.sts.org.

About the STS/ACC TVT Registry™

The TVT Registry is a benchmarking tool developed to track patient safety and real-world outcomes related to the TAVR procedure. Created by STS and the ACC, the TVT Registry is designed to monitor the safety and efficacy of TAVR for the treatment of aortic stenosis. www.tvtregistry.org