



AMERICAN COLLEGE *of* CARDIOLOGY

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Report Finds TAVR is Dominant Form of Aortic Valve Replacement, Outcomes Steadily Improving in the United States

Data from the STS/ACC TVT Registry Provides Insights on 'State of TAVR in the United States'

WASHINGTON (Nov. 16, 2020) — Since the approval of the first transcatheter aortic valve replacement (TAVR) device in 2011, more than 276,000 patients have undergone a TAVR procedure in the United States. According to a report from The Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) TVT Registry, volumes have increased every year and in 2019 TAVR exceeded all forms of surgical aortic valve replacement (SAVR) for the first time. In addition, over time the 30-day mortality and stroke rates have decreased, while pacemaker need remains largely unchanged. The full report was published in the *Journal of the American College of Cardiology* and *The Annals of Thoracic Surgery* simultaneously.

“The STS/ACC TVT Registry allows us to see major trends occurring in the real-world TAVR patient population, including a rapid growth in both the number of hospital sites performing TAVR and case volume as we treat a broader spectrum of patients. We have also seen TAVR become the leading choice for aortic valve replacement compared to the open surgical approach,” said John D. Carroll, MD, Chair of the STS/ACC TVT Registry Steering Committee and the lead author on the report. “Furthermore, the data on outcomes after TAVR document a substantial improvement in quality of care in the last nine years.”

Since the first TAVR device approval, access has been extended from patients considered inoperable or at extreme risk (2011), at high-risk (2012), intermediate-risk (2016) and low-risk (2019) for SAVR. Researchers examined data in the STS/ACC TVT Registry for all TAVR procedures performed at sites active through 2019. An early TAVR experience was defined as patients treated from late 2011 through 2013 and was compared to current TAVR experience, which was defined as patients treated in 2019.

Data in 2019 are from hospitals located in 49 U.S. states, as well as two sites in the District of Columbia and two sites in Puerto Rico. In August 2020 there were 715 U.S. TAVR sites. As of the opening of a site in Wyoming in 2020 TAVR programs exist in all 50 states. The only U.S. TAVR sites not included in the STS/ACC TVT Registry are those in military hospitals and the Veterans Authority (VA) medical system: as of mid-2019 there were eight VA TAVR programs.

The annual volume of TAVR has increased each year and in 2019 TAVR volume (72,991) exceeded all forms of SAVR (57,626), coinciding with the U.S. Food and Drug Administration (FDA) approval of TAVR for low-risk patients. The number of TAVR procedures performed per site varies, but as the number of sites performing TAVR has increased, the total annual volume has increased. In 2019 sites performed 84 TAVR procedures on average with 161 sites performing less than 50 cases. An expert consensus document published by stakeholders—including the ACC and STS—included a recommendation of a 50-case annual threshold minimum for sites performing TAVR.

Data showed the median age of patients undergoing TAVR has slightly gone down from early TAVR experiences. In 2019 mostly males (56%) underwent TAVR, a shift away from the early TAVR period when there was a nearly equal male/female distribution of patients undergoing the procedure. For all years, patients undergoing TAVR were predominantly white with the persistence of underrepresentation of blacks, based on overall U.S. demographics, at 4% despite the substantial growth of sites offering TAVR. This finding will stimulate further research into its possible causes ranging from barriers to health care access to differences in the prevalence of disease. From 2011 thru 2018 extreme and high-risk patients remain the largest cohort undergoing TAVR, but in 2019 intermediate-risk was the largest cohort. In 2019, the first year TAVR was FDA-approved for low-risk patients, this population made up 11.5% of all TAVR patients and had a median age of 75.

In the early TAVR period with very large vascular sheaths required for the first-generation TAVR delivery catheters, only 57.1% of TAVR procedures used femoral artery access. By the current TAVR period in 2019, femoral access accounted for 95.3% of vascular access sites for the procedure. In 2019 the axillary-subclavian was the most commonly used alternative access approach, a shift from the use of transapical and direct aortic approaches that were the common alternative access point in the early TAVR period.

The median length of stay for patients has declined from seven days to two days for all patients over the course of the report. For patients assessed as low-risk, the median length of stay in 2019 was only one-day—an overnight hospital stay—with some patients discharged the same day. In the early TAVR period, most patients were discharged to another care facility. In 2019 90.3% of patients were discharged home, while 6.6% were discharged to a rehabilitation or extended care facility and 2.45% to a nursing home. Researchers also found a steady and dramatic shift in mortality from the early TAVR period to 2019. In-hospital mortality fell from 5.4% to 1.3% and 30-day mortality decreased from 7.2% to 2.5%. In-hospital and 30-day stroke rates also fell from the early TAVR period to the current TAVR period. However, the 30-day pacemaker implantation rate has remained largely the same. The in-hospital rate has fallen in the context of the shorter length of stay at the hospital.

The STS/ACC TVT Registry has been innovative in gathering data from patients on their assessment of their individual health status, using the Kansas City Cardiomyopathy Questionnaire (KCCQ) before treatment. The registry also gathers data on whether there are changes post-TAVR in component metrics on quality of life (QOL), functional state and other patient reported outcomes. In 2018—the most recent year with one-year outcomes data for patients treated on or before September 30—80.7% of all patients who were alive at one-year post-TAVR and had complete KCCQ data reported a good QOL. In addition, a subgroup analysis revealed that this benchmark was achieved in 77.7% of high-extreme risk, 83.6% of intermediate-risk and 85.8% of low-risk patients.

According to the researchers, this report also provides a preliminary real-world assessment of patients having TAVR who were classified as being low-risk after the FDA approved these patients for TAVR in August 2019.

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The American College of Cardiology envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned *JACC Journals*, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

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About The Society of Thoracic Surgeons

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,300 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 advance cardiothoracic surgeons' delivery of the highest quality patient care through collaboration, education, research, and advocacy. For more, visit sts.org.

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