

ACCF/AATS/SCAI/STS release consensus document to help guide use of minimally invasive heart therapy

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With the U.S. Food and Drug Administration's recent approval of transcatheter aortic valve replacement (TAVR) for patients with aortic valvular stenosis, the American College of Cardiology Foundation (ACCF), along with the American Association for Thoracic Surgery (AATS), the Society for Cardiovascular Angiography and Interventions (SCAI) and the Society of Thoracic Surgeons (STS), today released an expert consensus document to provide important guidance on its use.

Aortic valvular stenosis – or aortic stenosis (AS) – occurs when the heart's [aortic valve](#) narrows, making it difficult for the heart to pump blood through the body. Until recently, some patients with severe AS who were at very high risk for conventional surgical aortic valve replacement had few, if any, options for treatment to help prevent serious heart problems including heart failure and death. TAVR, an innovative procedure that uses minimally invasive catheter-based technology to replace the aortic valve, represents a new therapeutic option for these severe AS patients who are either extremely high-risk candidates, or are inoperable for surgical aortic valve replacement due to associated comorbidities.

"This is a new, transformational technology for our patients; we have never had this type of an approach before; it's not like another balloon catheter," said David R. Holmes, Jr, MD, president of ACC and chair of the writing committee. "As this technology is introduced into practice,

detailed and agreed upon protocols are needed to ensure we achieve optimal clinical results. This consensus document provides the field with clear recommendations and [guidance](#) for its use."

The new report – a detailed follow-up to the joint position statement from ACC and STS released in late 2011 – examines the current state of the evidence; offers steps to facilitate integration of TAVR into the mix of available therapeutic options for select patients; and outlines how it should best be used and how to appropriately select patients to optimize clinical outcomes and encourage responsible application of this promising technology.

TAVR, which was approved by the FDA in November 2011, represents a fundamental change in the management of aortic valvular heart disease by offering an alternative to traditional surgical [aortic valve replacement](#) in carefully selected patients, according to the writing committee. Its implementation into the flow of patient care is complex, and involves consideration of several key factors such as clinical site selection, operator and team training and experience, patient selection and evaluation, procedural performance and complication management, and post-procedural care. Therefore, guidance is urgently needed to ensure it is smoothly integrated into clinical practice and followed to achieve real-world benefits and minimize risks to patients.

"Our goal in crafting this expert consensus document is to provide a clear roadmap for the use of TAVR as it reaches patients across the United States," said Michael J. Mack MD, president of STS and vice chair of the writing committee. "TAVR innovation is a major advance in treating aortic stenosis and sick, elderly patients should have access to this new treatment so they can resume normal, active lives. These guidelines are a coordinated effort from the cardiovascular community to help ensure the appropriate use of TAVR therapy for optimum patient safety."

The consensus document, which is endorsed by a dozen leading medical groups, outlines key recommendations for the success roll out of this therapy. Among others, these recommendations provide detailed criteria on:

- Careful patient selection
- Team-based approach given the complexity of procedure coupled with the high-risk profile of suitable patients, many of whom have extensive comorbid conditions that require ongoing management
- Specialized heart centers and physician expertise in treating valve disorders; this includes use of proctors as needed to serve on the heart care team during the first few cases, as well as proper facilities (hybrid operating rooms or modified cath labs)
- TAVR screening tests to inform treatment decisions
- Enhanced patient and family education in the risk and benefits of this procedure
- Ongoing evaluation and participation in national TAVR registry to assess real world outcomes

An estimated 45,000 patients have received TAVR worldwide. Multiple single and multicenter registries, and a single randomized trial, have documented favorable outcomes using a wide spectrum of endpoints including survival, symptom status, quality of life, and need for repeat hospitalization. Clinical use of TAVR, its continued evolution, and outcomes will be evaluated in the new STS/ACC TVT registry which will further inform future recommendations on application of this transformational technology.

"We have tried to collate the evidence into a coherent road map for judicious use, rational dispersion, and careful post-marketing scrutiny of this promising technology," said Sanjay Kaul, MD, a cardiologist at

Cedars-Sinai Heart Institute in Los Angeles and vice chair of the writing committee. It is now the collective responsibility of all the stakeholders to optimize its full potential for improving the duration as well as the quality of survival in patients with severe symptomatic aortic valvular stenosis."

While this technology has the potential to benefit many patients with AS, authors caution it is not for everyone and stress that more data is needed to ascertain the risk-benefit ratio prior to using this approach in certain groups. At present, and as outlined in the consensus document, TAVR is not recommended in adults who have:

- An acceptable surgical risk for conventional surgical AVR
- Known bicuspid aortic valve
- Severe mitral annular calcification or severe MR
- Moderate AS
- Other (e.g., severe AR and subaortic stenosis)

The other professional medical and consumer groups represented on the writing committee and that endorse this document include: the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Society of Cardiovascular Computed Tomography, Society of Cardiac Magnetic Resonance, Society of Cardiovascular Anesthesiologists, and Mended Hearts.

Provided by American College of Cardiology

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