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Four Professional Societies Publish Recommendations to Guide Minimally Invasive Valve Therapy Programs for Heart Patients

Effort Encourages Multi-Disciplinary Heart Team Approach and Offers Providers and Institutions Roadmap to Optimal Patient Care

WASHINGTON, D.C., BEVERLY, MA, and CHICAGO (May 15, 2014) – As minimally invasive therapies are increasingly used to treat diseased heart valves, newly published recommendations provide guidance on best practices for providing optimal care for patients. The document released today offers first-time guidance from four professional medical associations on developing and maintaining a transcatheter mitral valve therapy program, emphasizing collaboration between interventional cardiologists and cardiac surgeons. The document is an important step toward achieving consistent, effective care, particularly as the Centers for Medicare & Medicaid Services (CMS) prepare to issue a national coverage decision for transcatheter valve repair and replacement procedures.

The consensus paper, by the Society for Cardiovascular Angiography and Interventions (SCAI), American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC) and The Society of Thoracic Surgeons (STS), outlines criteria for healthcare providers and institutions to offer consistent and appropriate care to patients in the new and rapidly developing field of transcatheter valve therapy. The treatment uses a catheter to place a clip on the mitral valve to reduce the leakage, offering the only alternative treatment option to open heart surgery. The minimally invasive procedure is particularly effective for high-risk patients, such as the elderly, frail, or those with a history of other illness for whom open heart surgery may be too risky.

“As these techniques continue to increase in use, we must promote consistent, best practices and standards of care for providers and institutions so that patients get the best possible care,” said Carl L. Tommaso, MD, FACC, FSCAI, chair of the writing committee and medical director of the cardiac catheterization lab, NorthShore University HealthSystem Skokie Hospital, Evanston, IL. “These recommendations will help build and maintain programs centered on the best interests of patients.”

A committee comprised of cardiac surgeons and interventional cardiologists developed the recommendations in response to the changing landscape of treatment for valve disease. There was a need to establish core competencies and technical skills required for providers and institutions who offer transcatheter treatment options to patients. The paper emphasizes the need for a multi-disciplinary team approach, involving both surgeons and interventional cardiologists with extensive knowledge and diagnostic skills related to valvular disease.

“Multidisciplinary teams have been shown to improve outcomes in complex procedures,” said David A. Fullerton, MD, FACC, president of STS. “Working together to set the standard of care improves patient treatment and outcomes by building and maintaining quality, effective programs.”

The document also provides a roadmap for the clinical experience and provider skills necessary for successful transcatheter programs. Operators, regardless of their specialty, should have a deep understanding of valvular heart disease, the ability to interpret echocardiographic and other radiographic images, use of 3D echocardiography and expertise in the interpretation of CT scans related to valve disease. Additionally, minimum requirements for individual providers should include an understanding of radiation safety needed for optimal imaging, exposure protection and knowledge of the use of x-ray contrast agents.

On the institutional level, the recommendations focus on facility requirements and procedural volume for both individual operators as well as new and existing programs. Each institution should have an active valvular heart disease surgical program with at least two institutionally based cardiac surgeons experienced in valvular surgery, and should have available a full range of diagnostic imaging and therapeutic facilities.

“The institutional resources necessary to manage successful transcatheter programs are significant, on par with heart transplant and cardiac device assist programs, and should be performed in institutions that perform higher volumes of surgical valve operations with established track records,” said Dr. Tommaso. “Likewise, interventional cardiology programs should have established and successful track records with structural heart disease.”

The authors stress that long-term outcomes reporting and participation in data registries are mandatory for existing and new programs to ensure accurate data collection on survival and complications as well as determination of risk and long-term durability of devices.

“As we assess novel new treatments and techniques evolve, professional associations will continue to champion quality improvement for all providers in the best interest of patients,” said Dr. Fullerton.

The document titled, “Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement, Part II – Mitral Valve,” will simultaneously e-publish in *Catheterization and Cardiovascular Interventions (CCI)*, *Journal of Thoracic and Cardiovascular Surgery (JTCVS)*, *Journal of the American College of Cardiology (JACC)* and *The Annals of Thoracic Surgery*.

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About SCAI

The Society for Cardiovascular Angiography and Interventions is a 4,000-member professional organization representing invasive and interventional cardiologists in approximately 70 nations. SCAI's mission is to promote excellence in invasive/interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI's public education program, Seconds Count, offers comprehensive information about cardiovascular disease. For more information about SCAI and Seconds Count, visit www.SCAI.org or www.SecondsCount.org. Follow [@SCAI](https://twitter.com/SCAI) and [@SCAINews](https://twitter.com/SCAINews) on Twitter for the latest heart health news.

About AATS

The American Association for Thoracic Surgery (AATS) is an international organization of over 1,300 of the world's foremost thoracic and cardiothoracic surgeons, representing 35 countries. AATS encourages and stimulates education and investigation into the areas of intrathoracic physiology, pathology and therapy. Founded in 1917 by a respected group of the last century's earliest pioneers in the field of thoracic surgery, the AATS' original mission was to "foster the evolution of an interest in surgery of the Thorax". One hundred years later, the AATS continues to be the premiere association among cardiothoracic surgeons. The purpose of the Association is the continual enhancement of the ability of cardiothoracic surgeons to provide the highest level of quality patient care. To this end, the AATS encourages, promotes, and stimulates the scientific investigation and study of cardiothoracic surgery. Visit www.aats.org.

About ACC

The mission of the American College of Cardiology is to transform cardiovascular care and improve heart health. The College is a 47,000-member medical society comprised of physicians, surgeons, nurses, physician assistants, pharmacists and practice managers. The College is a leader in the formulation of health policy, standards and guidelines. The ACC provides professional education, operates national registries to measure and improve quality of care, disseminates cardiovascular research, and bestows credentials upon cardiovascular specialists who meet stringent qualifications. For more information, visit www.cardiosource.org.

About STS

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 6,700 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. Visit STS at www.sts.org.