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**CONTACTS:**

**ACC:** Rachel Cagan, [rcagan@acc.org](mailto:rcagan@acc.org), 202.375.6395

**AATS:** Cindy VerColen, [cvercolen@prri.com](mailto:cvercolen@prri.com), 978.317.6001

**SCAI:** Kathy Boyd David, [kbdavid@scai.org](mailto:kbdavid@scai.org), 717.422.1181

**STS:** Cassie Brasseur, [cbrasseur@sts.org](mailto:cbrasseur@sts.org), 312.202.5865

## **Key Guidance Document Released on Transcatheter Therapies for Mitral Regurgitation**

*Four cardiovascular societies provide overview designed to ‘set the stage’ for targeted discussions about technologies’ dissemination*

**WASHINGTON, D.C. (Nov. 25, 2013)** – Four cardiovascular professional societies today released an overview of transcatheter therapies for mitral regurgitation. Intended to “help frame subsequent discussions” among the field’s various stakeholders, the document highlights critical issues that should be considered as the technologies are integrated into clinical practice.

The document was drafted by the American College of Cardiology, the American Association for Thoracic Surgery, the Society for Cardiovascular Angiography and Interventions, and The Society of Thoracic Surgeons and examines the responsible dissemination of these transcatheter therapies. Specifically, the overview discusses the technologies’ critical components, operator training, protocols for care, and assessment of outcomes.

“The authors and societies envision this document serving as a broad guideline for the responsible deployment of these new therapies for our patients and teams,” said John H. Calhoun, MD, Professor and Chair of Cardiothoracic Surgery at The University of Texas Health Science Center at San Antonio and overview Co-chair. “With this overview as a foundation, our societies will plan future documents to address appropriate data collection and use, best practices, team composition, and further definition of patient characteristics.”

The FDA recently approved the use of the MitraClip for the treatment of highly selected patients with severe, degenerative mitral regurgitation (MR) who are considered prohibitive risk for open surgery by an experienced Heart Team. Several other technologies to reduce MR, including annuloplasty devices and neochordal implants, are in various stages of development. The societies note that these therapies will likely have a significant impact on the care of selected patients with MR, just as transcatheter aortic valve replacement (TAVR) has for patients with aortic stenosis.

“Both TAVR and transcatheter MR therapies represent transformative technologies that can extend care to select populations of patients considered prohibitive risk for open surgery,” noted Patrick O’Gara, MD, Director of Clinical Cardiology at Brigham and Women’s Hospital, Professor of Medicine at Harvard Medical School, and overview Co-chair. “The lessons learned from the dissemination of TAVR will help guide a similar process for the integration of these transcatheter therapies for severe MR into clinical practice.”

Mitral regurgitation occurs when the heart's mitral valve doesn't close properly, allowing blood to flow back into the left atrium instead of forward into the aorta. This reduces the blood pumped to the body and causes the heart to enlarge. Symptoms of heart failure and arrhythmias, such as atrial fibrillation, may develop over time. Timely correction of the MR can prevent or improve these symptoms. In MR procedures, the faulty mitral valve is either repaired with a variety of techniques or replaced to reinstate proper blood flow through the heart.

The *Transcatheter Therapies for Mitral Regurgitation Societal Overview* examines both the talent and technology necessary for successful transcatheter MR therapies. Citing the landmark SYNTAX trial, the authors note that the Heart Team is crucial. This team-based approach to cardiac care involves many practitioners, including primary cardiologists, interventional cardiologists, cardiac surgeons, imaging specialists, and nurses, among others. The authors also noted that transcatheter MR therapies should be performed only at regional heart centers that have a high volume of heart valve procedures. As patient outcomes vary inversely with operator volume, the societies suggested that new transcatheter MR devices should only be available to high-volume centers that have met national criteria.

Discussing care protocols, the overview states that specific protocols for pre-, intra-, and post-procedural patient assessment and care should be put in place, as well as strategies to manage complications. Evaluation should include assessment of mitral valve anatomy and function, cardiac chamber sizes, biventricular function, pulmonary artery pressures, and any concomitant aortic or tricuspid valve pathology. Care protocols should include "clear delineation" of the various roles of the Heart Team members. In addition, patients should be transferred post-procedurally to a specialized cardiac/surgical intensive care unit, where the team can provide optimal and coordinated care.

Acknowledging their important role in the adoption of transcatheter MR therapies, the authors noted "it is incumbent on professional societies to set minimal performance standards." They added that societies should be developing the training curriculum, establishing metrics for evaluation, and certifying completion of the training module.

Furthermore, the authors advocated careful data collection, analysis, and reporting through the new STS/ACC Transcatheter Valve Therapy (TVT) Registry. Created in December 2011, the TVT Registry was designed to benchmark quality, enable cost analysis, and support comparative effectiveness research. As these data are interpreted and reported, the authors noted that indications and appropriate use criteria should be developed.

"Our societies embrace a process of integrating these new therapies into practice in a way that will ensure high-quality, patient-centric care provided by an experienced Heart Team with participation in a national registry to inform best practices," Dr. O'Gara said.

The full paper will publish online today on the websites of the ACC ([www.cardiosource.org](http://www.cardiosource.org)), AATS ([www.aats.org](http://www.aats.org)), SCAI ([www.scai.org](http://www.scai.org)) and STS ([www.sts.org](http://www.sts.org)). It will also be published in future print issues of *The Journal of the American College of Cardiology*; *Journal of Thoracic and Cardiovascular Surgery*, the journal for the American Association for Thoracic Surgery; *Catheterization and Cardiovascular Interventions (CCI)*, the journal of The Society for Cardiovascular Angiography and Interventions; and *The Annals of Thoracic Surgery*, the journal of The Society of Thoracic Surgeons.

### **About the American College of Cardiology**

The mission of the American College of Cardiology is to transform cardiovascular care and improve heart health. The College is a 40,000-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](http://www.cardiosource.org).

### **About the The American Association for Thoracic Surgery**

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](http://www.aats.org).

### **About the Society for Cardiovascular Angiography and Interventions**

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](http://www.scai.org) or [www.SecondsCount.org](http://www.SecondsCount.org). Follow [@SCAI](https://twitter.com/SCAI) and [@SCAINews](https://twitter.com/SCAINews) on Twitter for the latest heart health news.

### **About The Society of Thoracic Surgeons**

Founded in 1964, STS is a not-for-profit organization representing more than 6,800 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. [www.sts.org](http://www.sts.org)