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New Expert Consensus Statement Provides Recommendations to Guide Minimally Invasive Valve Treatments for Children and Adults

Statement on Transcatheter Pulmonic Valve Replacement Stresses Importance of Heart Team to Collaborate on Treatment Decisions

Washington, DC (March 24, 2015) – As congenital heart disease (CHD) treatment advances, children with these conditions are living into adulthood, and over time, they may need additional treatment. A new expert consensus paper released today 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) provides guidance on transcatheter pulmonic valve replacement, or tPVR, for children and adults who were previously treated for CHD.

Pulmonary valve replacement may be necessary in patients who have had certain types of CHD repaired with reconstruction of the right ventricular outflow tract (RVOT) – an area of the heart that carries blood out of the right ventricle. As patients with CHD live longer than they did in the past, dysfunction of the repair can occur over time. In the past, these patients would require a repeat open-heart surgery. Today, tPVR offers a less invasive option for many patients.

"Transcatheter valve treatments are allowing us to offer less invasive options to patients who were previously treatable only with open-heart surgery, or may not have been eligible for treatment at all," said Ziyad M. Hijazi, MD, MPH, FACC, MSCAI, chair of the writing committee, acting chief medical officer and chairman of the Department of Pediatrics at Sidra Medical and Research Center in Doha, Qatar. "These procedures are complementing standard surgical approaches, allowing physicians to provide greater options for our patients."

As treatment advances, cardiologists and surgeons have the opportunity to collaborate in determining the best treatment option for each patient. The consensus paper stresses that tPVR treatment recommendations should be made by a heart team consisting of interventional cardiologists, cardiac surgeons, noninvasive cardiologists, and cardiac anesthesiologists and radiologists.

"There is strong consensus that these new valve therapies should be performed under the guidance of a multi-disciplinary heart team, involving both interventional cardiologists and surgeons," said Dr. Hijazi. "Increasing evidence shows a team-based approach provides the greatest quality care for patients with complex heart disease, including patients considering tPVR." The paper further recommends that institutions offering tPVR perform at least 150 congenital/structural catheterization procedures per year, including 100 that are interventional, as well as 100 open-heart congenital surgical procedures. Institutions should have the heart-lung bypass support known as extracorporeal membrane oxygenation (ECMO); echocardiography, cardiac CT and cardiac MRI imaging capabilities; a cardiovascular catheterization laboratory (cath lab); and hemodynamic (blood pressure and electrocardiography) evaluation. Additionally, institutions should participate in a national registry. Because tPVR is a new treatment option, the committee stressed the importance of continuing to collect data on the procedure, including total numbers of tPVR in the United States and numbers of procedures by operator and institution.

Physicians performing tPVR should perform at least 100 interventional cases per year, including 50 congenital/structural interventional cases. They should have experience with balloon valvuloplasty as well as stenting within pulmonary arteries and RVOT. The paper also recommends physicians attend peer-to-peer training and a simulated case if available. The first three procedures performed should be under the guidance of an experienced physician.

"As physician experience with tPVR increases over time, complication rates are declining significantly, reflecting the importance of experience in improving patient outcomes," said Dr. Hijazi.

A committee of cardiac surgeons and interventional cardiologists developed the recommendations, which were created to help physicians and hospitals offer consistent and appropriate care to tPVR patients. The new paper is the third in a series of expert consensus papers for hospitals and physicians performing transcatheter valve procedures. The first two papers discussed aortic and mitral valve procedures.

The document, titled "Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement, Part III – Pulmonic 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 4,300-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 <u>SCAI.org</u> or <u>SecondsCount.org</u>. Follow <u>@SCAI</u> and <u>@SCAINews</u> on Twitter for the latest heart health news.

About AATS

The American Association for Thoracic Surgery is an international organization of over 1,300 of the world's foremost cardiothoracic surgeons representing 41 countries. Founded in 1917, its members have a proven record of distinction within the specialty and have made significant contributions to the care and treatment of cardiothoracic disease throughout the world. For more information about AATS, visit <u>www.aats.org</u>.

About ACC

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 <u>acc.org</u>.

About STS

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 6,900 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.