Aortic Valve and Ascending Aorta Guidelines for Management and Quality Measures: Executive Summary

Writing Committee Members: Lars G. Svensson, MD, PhD (Chair), David H. Adams, MD (Vice-Chair), Robert O. Bonow, MD (Vice-Chair), Nicholas T. Kouchoukos, MD (Vice-Chair), D. Craig Miller, MD (Vice-Chair), Patrick T. O'Gara, MD (Vice-Chair), David M. Shahian, MD (Vice-Chair), Hartzell V. Schaff, MD (Vice-Chair), Cary W. Akins, MD, Joseph Bavaria, MD, Eugene H. Blackstone, MD, Tirone E. David, MD, Nimesh D. Desai, MD, PhD Todd M. Dewey, MD, Richard S. D'Agostino, MD, Thomas G. Gleason, MD, Katherine B. Harrington, MD, Susheel Kodali, MD, Samir Kapadia, MD, Martin B. Leon, MD, Brian Lima, MD, Bruce W. Lytle, MD, Michael J. Mack, MD, T. Brett Reece, MD, George R. Reiss, MD, Eric Roselli, MD, Craig R. Smith, MD, Vinod H. Thourani, MD, E. Murat Tuzcu, MD, John Webb, MD, and Mathew R. Williams, MD

The Society of Thoracic Surgeons Clinical Practice Guidelines are intended to assist physicians and other health care providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. These guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the same results. Moreover, these guidelines are subject to change over time, without notice. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of the individual circumstances presented by the patient.

(Ann Thorac Surg 2013;95:1491–505)

1. Introduction and Methodology

The question may be asked why another Guideline manuscript is needed. The reasons are fivefold: (1) to outline pros and cons of treatment options; (2) to outline areas where further research is needed, potentially from updated Society of Thoracic Surgeons (STS) data collection variables as there are few randomized trials that give more absolute answers to questions; (3) to provide technical guidelines for aortic valve and aortic surgery; (4) to provide background for recommended quality measures and suggest quality measures; and (5) to present the new STS valve data collection variables that address issues related to the preoperative testing and technical aspects of aortic valve surgery.

In this document, surgeons and cardiologists have worked together to further elaborate on the previously published 2008 ACCF/AHA Guidelines for the Management of Patients With Valvular Heart Disease and 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease [1–3] documents and to concentrate on surgical aspects including the new evolving technology of percutaneous valves, namely, transcatheter aortic valve replacement (TAVR).

The evaluation of aortic valve procedures suffers from a dearth of prospective randomized trials that have shown definitive superiority of one procedure over others, although this has been attempted (eg, mechanical versus biological valves, and homografts versus Ross

For authors' disclosure of industry relationships, go to: http://www.sts.org/annals-thoracic-surgery/auxiliary-annals and search for Appendix for Svensson LG, et al. Aortic Valve and Ascending Aorta Guidelines for Management and Quality Measures: Executive Summary (http://www.sts.org/auxiliaryannals/Svensson-2013-Exec-Summary-Aortic-Valve-Ascending-Aorta-Guidelines-author-industry-relationships-Appendix.pdf).

The full guideline will appear in a subsequent issue of *The Annals of Thoracic Surgery* as a Supplement and will be available online at http://ats.ctsnetjournals.org and http://www.sciencedirect.com. The full text of all STS Practice Guidelines are also available at: http://www.sts.org/resources-publications on the official STS Web site (www.sts.org).

Address correspondence to Dr Svensson, The Cleveland Clinic, 9500 Euclid Ave, Desk F-25 CT Surgery, Cleveland, OH 44195; e-mail: svenssl@ccf.org.

Published by Elsevier Inc

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2012.12.027

Abbreviations and Acronyms

AATS = American Association for Thoracic Surgery
ACCF = American College of Cardiology Foundation
ACE = angiotensin-converting enzyme
AHA = American Heart Association
AR = aortic regurgitation
AS = aortic stenosis
AVR = aortic valve replacement
BAV = balloon valvuloplasty
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
CT = computed tomography
EF = ejection fraction
FDA = Food and Drug Administration
LV = left ventricular
MRI = magnetic resonance imaging
STS = The Society of Thoracic Surgeons
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography

procedure, and so forth) [4–20]. Hence, the guidelines rely primarily on nonrandomized trials, observational studies, registries, propensity analyses, and consensus statements of experts. The application of class of recommendation and level of evidence characterization is according to those recommended by ACCF/AHA.

The guidelines address only the adult population and not the pediatric population. When needed, they draw heavily from the previously published 2010 ACC/AHA document, and thus, indications for surgery are not covered in detail except where new evidence suggests an update is needed. The previous guidelines for severity of disease and the management of outcomes for patients with asymptomatic disease are summarized and covered in detail in the 2010 documents [1–3]. A more detailed discussion of aortic valve replacement, outcomes, trends and the guidelines in this document are available (see full guideline version with tables, figures, and full list of references) and will be published as a Supplement to *The Annals of Thoracic Surgery*.

For cardiologists and cardiac surgeons there have been few options and no guidelines on how to manage the high-risk, previously inoperable, patients. The TAVR technology and particularly the pivotal PARTNER (Placement of Aortic Transcatheter) trials and the ongoing CoreValve trial have further focused efforts on managing this population. Previous studies have suggested that between 38% (Europe) and two thirds (Southern California) of patients with severe aortic valve stenosis go untreated [21, 22]. With the advent of TAVR both the traditionally open aortic valve replacement (AVR) procedures and balloon valvuloplasty (BAV) have also pari passu evolved.

Literature searches were conducted using standardized MeSH terms from the National Library of Medicine PUBMED database list of search terms. Section authors then drafted their recommendations, using prior published guidelines as a reference when available, and circulated to the entire writing committee as drafts at the end of 2011. Revisions were made until consensus was reached on class, level of evidence, references and language. Finally, the full document was submitted in 2012 for approval by the STS Workforce on Evidence Based Surgery prior to publication. The guidelines were posted on the STS website for an open comment period. The guidelines then were also submitted to the STS Council on Quality, Research, and Patient Safety Operating Board and the STS Executive Committee before submission for publication.

1.1. Evaluation of a Valve Procedure

Paramount to evaluating a valve procedure is (1) safety; (2) efficacy (hemodynamic performance, effective orifice area, and energy loss); (3) durability, measured as freedom from structural valve deterioration; (4) event-free survival; and (5) ease of procedure.

For aortic valve procedures to be accepted into general practice, however, by interventional cardiologists and surgeons, the sequence of steps would entail the following: (1) ease of prosthetic aortic valve insertion or valve repair; (2) safety of the operation; (3) effective orifice area, including gradients and energy loss; and (4) long-term durability, with no difference in survival compared with other devices, but better than the untreated population.

Clearly, there are few, if any, medical procedures that are as effective in relieving symptoms, improving quality of life, and also increasing long term survival as much as AVR for aortic stenosis (AS) or aortic regurgitation (AR), but for perhaps the exception of heart transplantation, but the latter adds the problem of managing new medications and increased monitoring. Recent data from 3,600 Medicare patients shows that there is a reduced hospital readmission rate and increased survival in high-risk Medicare patients (age ≥65 years) treated with AVR for severe AS, despite the extra cost. Of note, open AVR does not reduce the cost when compared to medical management despite the multiple readmissions for heart failure in the latter.

The potential population needing AVR for severe AS is estimated at 350,000 and increasing. Although the exact number of aortic valve procedures, including repairs and replacements is unknown, 48,000 has been reported [23], and a number of 95,000 Medicare patients was reported in another publication for a 2-year period [24]. Data from hospital purchases shows that in the year ending mid 2011, 92,514 aortic valve prostheses were sold in the United States. The STS Adult Cardiac Surgery Database (ACSD) does not capture the number since only patients who undergo single valve replacement or valve plus coronary bypass are tracked. Nevertheless, the STS data shows AVR is increasing, probably because of the aging population and increasing awareness of good results of AVR, and the option of TAVR. Despite this, on average an STS site does 23 isolated aortic valves and on average a cardiac surgeon only does 8 AVR per annum.