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

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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.

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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

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).

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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>).

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.

The new STS valve data module adds various variables that members of the Writing Committee and the STS Workforce on National Databases thought would be important information for future studies, and that would allow for further research to improve both the process of an aortic valve insertion as well as the procedure quality of care. Clearly, this will raise new questions that will result in the evolution and iteration of newer guidelines based on future studies and the data collected by the STS ACSD.

2. Summary and Update of ACCF/AHA Guidelines for Indications and Timing of Surgery

Major advances in the evaluation and management of patients with valvular heart disease during the past several decades have resulted in substantial improvement in the outcomes of patients in terms of survival and quality of life. These advances, coupled with the growing prevalence of diseases of heart valves in an aging population and the impact on quality of life, health care resources, and need for quality improvement, stimulated the joint guidelines task force of the ACCF/AHA to establish a writing committee to formulate guidelines for the management of patients with valvular heart disease (first published in 1998 [25], extensively revised in 2006 [2], and updated in 2008 [1]). Comparable guidelines from the European Society of Cardiology were published in 2007 [26].

Although the ACCF/AHA guideline recommendations represent a major step forward in improving and standardizing quality of care, there are fundamental weaknesses in the underpinnings of these guidelines due to the scarcity of large-scale multicenter trials addressing the diagnosis and treatment of patients with valvular disease. Thus, virtually all of the recommendations in the ACCF/AHA document are based on expert consensus (level of evidence C) rather than on prospective multicenter randomized trials (level of evidence A). Nonetheless, implementation of prospective randomized trials is necessary to move the field forward.

2.1. Classification of Recommendations

The ACCF/AHA Guidelines for the Management of Patients with Valvular Heart Disease recommendations follow the standard format established for other ACCF/AHA recommendations:

- Class I: conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful, and effective
- Class II: conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment
- Class IIa: weight of evidence/opinion is in favor of usefulness/efficacy
- Class IIb: usefulness/efficacy is less well established by evidence/opinion

- Class III: conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful

3. Aortic Stenosis—Recommendations

Class I

1. AVR is recommended for patients with severe AS at the onset of symptoms of dyspnea, angina, or lightheadedness or syncope [27–35]. (Level of evidence B)
2. AVR is recommended, regardless of symptoms, with the identification of left ventricular (LV) systolic dysfunction (ejection fraction [EF] <50%). (Level of evidence C)
3. AVR is recommended for patients with severe AS who are scheduled to undergo coronary artery bypass graft surgery (CABG), surgery on other cardiac valves, or surgery on the aortic root or ascending aorta. (Level of evidence C)

Class IIa

1. AVR is reasonable in patients with moderate AS undergoing CABG or surgery on the aorta or other heart valves [36–39]. (Level of evidence B)

Class IIb

1. Exercise testing in asymptomatic patients with AS to determine the need for AVR may be considered to elicit exercise-induced symptoms and abnormal blood pressure responses [40–42]. (Level of evidence B)
2. AVR may be considered for asymptomatic patients with severe AS and abnormal response to exercise (eg, asymptomatic hypotension). (Level of evidence C)
3. AVR may be considered for adults with severe asymptomatic AS if there is a high likelihood of rapid progression (age, calcification, and CAD) or if surgery might be delayed at the time of symptom onset. (Level of evidence C)
4. AVR may be considered in patients undergoing CABG who have mild AS when there is evidence, such as moderate to severe valve calcification, that progression may be rapid. (Level of evidence C)
5. AVR may be considered for asymptomatic patients with extremely severe AS (aortic valve area <0.6 cm², mean gradient >60 mm Hg, and jet velocity >5.0 m/s) when the patient's expected operative mortality is less than 1%. (Level of evidence C)

Class III

1. AVR is not useful for the prevention of sudden death in asymptomatic patients with AS who have normal LV systolic function [43]. (Level of evidence B)

4. Aortic Regurgitation—Recommendations

Class I

1. AVR or repair is indicated for symptomatic patients with severe AR irrespective of LV systolic function (Fig 2) [44–50]. (Level of evidence B)
2. AVR or repair is recommended for asymptomatic patients with chronic severe AR and LV systolic dysfunction (EF \leq 50%) at rest [44–60]. (Level of evidence B)
3. AVR or repair is recommended in patients with chronic severe AR who are undergoing CABG or surgery on the aorta or other heart valves. (Level of evidence C)

Class IIa

1. AVR or repair is reasonable for asymptomatic patients with severe AR with normal LV systolic function (EF $>$ 50%) but with severe LV dilation (end-diastolic dimension $>$ 75 mm or end-systolic dimension $>$ 55 mm) [45, 46, 50–54, 56–59, 61]. (Level of evidence B)

Class IIb

1. AVR or repair may be considered in patients with moderate AR who are undergoing CABG or surgery on the aorta or other heart valves. (Level of evidence C)
2. AVR or repair may be considered for asymptomatic patients with severe AR and normal LV systolic function at rest (EF $>$ 50%) when the degree of LV dilation exceeds an end-diastolic dimension of 70 mm or end-systolic dimension of 50 mm, when there is evidence of progressive LV dilation, declining exercise tolerance, or abnormal hemodynamic responses to exercise. (Level of evidence C)

Class III

1. AVR is not indicated for asymptomatic patients with mild, moderate, or severe AR and normal LV systolic function at rest (EF $>$ 50%) when the degree of LV dilation is not moderate or severe (Fig 2) [62–66]. (Level of evidence B)

5. Aortic Valve Endocarditis—Recommendations

Class I

1. AVR is recommended in patients with aortic valve infective endocarditis and severe heart failure or cardiogenic shock due to aortic valve dysfunction when there is a reasonable likelihood of recovery with satisfactory quality of life after surgery [2, 67–70]. (Level of evidence B)
2. Surgery is recommended in patients with annular or aortic abscesses, heart block, infections resistant to antibiotic therapy, and fungal endocarditis [67–71]. (Level of evidence B)

Class IIa

1. Surgery is reasonable in patients with infective endocarditis who present with recurrent emboli and persistent vegetations despite appropriate antibiotic therapy. (Level of evidence C)

Class IIb

1. Surgery to prevent embolization might be considered for patients with large vegetation size ($>$ 1.5 cm), especially if other relative indications for surgery are present (eg, severe AR) and the surgical risk is low [72, 73]. (Level of evidence C)

6. Surgical Risk Scores—Recommendations

Class IIa

1. Performing risk score analysis is reasonable to evaluate patients undergoing surgical AVR or TAVR to quantitate PROM [74–76]. (Level of evidence B)

Class IIb

1. Performing risk score analysis may be reasonable to aid in determining which patients should undergo AVR, TAVR or medical therapy alone in high-risk patients. (Level of evidence C)

7. Echocardiography—Recommendations

Class I

1. Transthoracic echocardiography (TTE) is recommended for the diagnosis and assessment of AS or AR severity. (Level of evidence B)
2. Echocardiography is recommended in patients with AS or AR for the assessment of LV wall thickness, size, and function (1). (Level of evidence B)
3. TTE is recommended for reevaluation of patients with known AS or AR and changing symptoms or signs (1). (Level of evidence B)
4. TTE is recommended for the assessment of changes in hemodynamic severity and LV function in patients with known AS or AR during pregnancy (1). (Level of evidence B)
5. TTE is recommended for reevaluation of asymptomatic patients: every 6 months for severe AS or AR; every 1 to 2 years for moderate AS or AR; and every 3 to 5 years for mild AS or AR [1]. (Level of evidence B)
6. Intraoperative TEE is recommended to check repairs or replacements. (Level of evidence B)

8. Exercise Testing—Recommendations

Class IIb

1. Exercise testing in asymptomatic patients with AS or AR may be considered to elicit exercise-induced

symptoms and abnormal blood pressure responses. (Level of evidence B)

Class III

1. Exercise testing should not be performed in symptomatic patients with AS or AR. (Level of evidence B)

9. Dobutamine Stress Echocardiography and Cardiac Catheterization for Low-Flow/Low-Gradient Aortic Stenosis—Recommendations

Class IIa

1. Dobutamine stress echocardiography is reasonable to evaluate patients with low-flow/low gradient AS and LV dysfunction for possible AVR or TAVR [75, 77–85]. (Level of evidence B)
2. Cardiac catheterization for hemodynamic measurements with infusion of dobutamine can be useful for evaluation of patients with low-flow/low-gradient AS and LV dysfunction. (Level of evidence C)

10. Cardiac Catheterization—Recommendations

Class I

1. Coronary angiography is recommended before AVR in patients with AS or AR at risk for CAD. (Level of evidence B)
2. Patients aged more than 45 years undergoing a valve procedure should undergo coronary imaging. (Level of evidence C)
3. Cardiac catheterization for hemodynamic measurements is recommended for assessment of severity of AS or AR in symptomatic patients when noninvasive tests are inconclusive or when there is a discrepancy between noninvasive tests and clinical findings. (Level of evidence C)

Class IIb

1. For patients aged less than 45 years, computed tomography (CT) coronary angiography may be considered. (Level of evidence C)

Class III

1. Cardiac catheterization for hemodynamic measurements is not recommended for the assessment of severity of AS before AVR when noninvasive tests are adequate and concordant with clinical findings. (Level of evidence C)
2. Cardiac catheterization for hemodynamic measurements is not recommended for the assessment of LV function and severity of AS or AR in asymptomatic patients. (Level of evidence C)

11. Cannulation Options for Aortic Valve and Root Surgery—Recommendations

Class I

1. For most patients requiring a simple aortic valve procedure without ascending aortic disease, the distal ascending aorta is recommended as the site for cannulation [16]. (Level of evidence B)
2. For complex repairs involving the arch or a calcified aorta or porcelain aorta, use of the axillary artery with a side graft is recommended [16]. (Level of evidence B)

12. Mechanical Aortic Valves—Recommendations

Class I

1. Before mechanical AVR, all patients who have known CAD, have had a prior myocardial infarction, have angina pectoris as a symptom, or are more than age 45, should have preoperative screening of their coronary arteries by direct coronary angiography. (Level of evidence C)
2. All patients undergoing mechanical AVR should receive perioperative prophylactic antibiotics to cover both Gram-positive and Gram-negative organisms. (Level of evidence C)
3. All patients receiving a mechanical aortic valve should receive postoperative anticoagulation therapy, beginning after valve implantation. (Level of evidence C)
4. All patients with mechanical aortic valve prostheses should receive prophylactic antibiotics for all dental or surgical procedures to prevent prosthetic endocarditis. (Level of evidence C)

Class IIa

1. Nasal mupirocin is probably indicated for methicillin resistant organism or routinely before and after operations. (Level of evidence C)
2. Preoperative chlorhexidine showers and mouth washes should be considered. (Level of evidence C)

Quality Measures

1. All patients receiving a mechanical aortic valve should receive indefinite postoperative anticoagulation therapy. Controversy exists over the exact target international normalized ratio levels for mechanical aortic valve prostheses. Appropriate levels of therapeutic international normalized ratio vary according to concomitant patient risk factors [86]. The safety of lower levels of anticoagulation is improved with patient-controlled anticoagulation therapy [87].
2. All patients with mechanical aortic valve prostheses should receive prophylactic antibiotics for all dental or surgical procedures to prevent prosthetic endocarditis.

3. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.

13. Biological Valves—Recommendations

Class I

1. A bioprosthesis is recommended for AVR in patients of any age who will not take anticoagulation therapy, either warfarin or the direct factor Xa, or thrombin inhibitors or who have major medical contraindications to anticoagulation [2]. (Level of evidence C)
2. A bioprosthesis is recommended for AVR in patients aged 65 years or more without risk factors for thromboembolism [2]. (Level of evidence C)

Class IIa

1. Patient preference is a reasonable consideration in the selection of aortic valve prosthesis if appropriate surgical counseling is carried out.

Class IIb

1. A bioprosthesis may be considered for AVR in a woman of childbearing age who desires to have children [2]. (Level of evidence C)
2. A bioprosthesis may be reasonable for AVR in patients age less than 65 years who elect to receive this valve for lifestyle considerations after detailed discussions of the risks of anticoagulation therapy versus the likelihood that AVR may be necessary in the future [2]. (Level of evidence C)

Quality Measures

1. All patients should receive both Gram-positive and Gram-negative prophylactic antibiotics before AVR and broad-spectrum antibiotic strict prophylaxis before any surgical, endoscopic, dental, or other procedure associated with the chance of bacteremia.
2. All centers performing AVR should report their results to a national database such as the STS ACSD.
3. To evaluate meaningfully the choice of appropriate prosthesis, it is imperative to have standardized guidelines for reporting mortality and morbidity after valve interventions [88]. Much of the confusion and conflicting evidence comparing different valve types derives from the heterogeneity of the patient samples studied and the different definitions used in reporting complications and structural valve deterioration rates. Freedom from reoperation for structural valve deterioration underestimates the true incidence of structural valve deterioration. Structural valve deterioration should represent dysfunction determined by reoperation, autopsy, or clinical investigation, including periodic echocardiograms. It is also important to distinguish between patient outcome versus valve outcome to counsel individual patients on

valve choice. Performance of the prosthesis (valve-related events), when looking at nonfatal complications, is usually reported using the Kaplan-Meier *actuarial* method, with the number at risk at each interval indicated. The Kaplan-Meier method, however, is designed for population studies and overestimates the actual event probability for an individual patient; thus, to predict valve outcome for an individual patient, the cumulative incidence (or observed cumulative frequency) *actual* statistical method should be used. These actual (cumulative incidence) estimates are best suited for individual patient counseling and patient management decisions [89].

4. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.

14. Enlargement of the Aortic Annulus—Recommendations

Class I

1. Patch enlargement of the aortic annulus should be considered when the aortic annulus does not allow implantation of a heart valve with effective orifice area index greater than $0.65 \text{ cm}^2/\text{m}^2$ [90–92]. (Level of evidence B)

Class IIb

1. Patch enlargement of the aortic annulus may be considered when the aortic annulus does not allow implantation of the heart valve with effective orifice area index of $0.85 \text{ cm}^2/\text{m}^2$. (Level of evidence C)

15. Homograft (Allograft) Replacement of the Aortic Valve—Recommendations

Class I

1. Homograft replacement of the aortic root should be considered for patients with extensive active endocarditic destruction of the aortic annulus [93–97]. (Level of evidence B)
2. For patients undergoing homograft replacement of the aortic valve, a total root replacement technique is recommended [98, 99]. (Level of evidence B)

Class IIa

1. Homograft replacement of the aortic valve can be considered for patients with endocarditis without annular destruction, especially when the potential for reinfection is elevated [16, 100, 101]. (Level of evidence B)
2. Homograft replacement of the aortic valve can be considered for patients undergoing reoperative aortic root surgery in whom anatomic or physiologic constraints mitigate against more conventional composite graft replacement or for whom life expectancy is less than the projected durability of the homograft [102–104]. (Level of evidence B)

Class III

1. Homografts are not recommended for routine AVR. Currently available xenografts have excellent hemodynamics, durability comparable to homografts, and are simpler to replace [105–107]. (Level of evidence B)

Quality Measures

1. All patients undergoing homograft implantation should receive perioperative prophylactic antibiotics with broad-spectrum coverage.
2. All patients with a potential for CAD or with coronary anomalies should undergo preoperative evaluation of their coronary anatomy by coronary angiography.
3. Annual transthoracic echocardiogram to evaluate for AS and AR.
4. Antibiotic prophylaxis against endocarditis for prosthetic valves.
5. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.

16. Subcoronary Stentless Valve Implantation for Aortic Valve Replacement—Recommendations

Class I

1. Before subcoronary stentless AVR, all patients who have known CAD, have had a prior myocardial infarction, have angina pectoris as a symptom, or are aged more than 45 years should have preoperative screening of their coronary arteries, by direct coronary angiography. (Level of evidence C)
2. Intraoperative TEE is recommended to check the valve function. (Level of evidence C)
3. Prophylactic antibiotics for any invasive procedure, including dentistry, are recommended. (Level of evidence C)

Class IIb

1. Stentless valves may be a reasonable prosthesis choice for patients aged more than 70 years with nonregurgitant, trileaflet AS who desire a tissue prosthesis and are at risk for patient-prosthesis mismatch. (Level of evidence C)

Quality Measures

1. Prophylactic Gram-positive and Gram-negative coverage should be used at the time of surgery.
2. Intraoperative echocardiography, usually TEE, should be performed.
3. Postoperative aspirin or clopidogrel should be administered.
4. Patients should be discharged on a regimen of beta-blockers.
5. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.

17. Full Aortic Root Replacement with a Stentless Prosthesis—Recommendations

Class I

1. Before aortic root replacement, all patients who have known CAD, have had a prior myocardial infarction, have angina pectoris as a symptom, or are aged more than 45 years, should have preoperative screening of their coronary arteries, by direct coronary angiography. (Level of evidence C)
2. Intraoperative TEE is required to check the valve function. (Level of evidence C)
3. Prophylactic antibiotics for any invasive procedure including dentistry are recommended. (Level of evidence C)

Class IIa

1. Stentless aortic valve full root replacement may be considered in patients aged more than 70 years with aortic root dilation. (Level of evidence C)

Class IIb

1. Stentless aortic valve full root replacement may be considered in patients aged more than 70 years at high risk for PPM who desire a tissue prosthesis. (Level of evidence B)

Quality Measures

1. Prophylactic Gram-positive and Gram-negative coverage should be used at the time of surgery.
2. Intraoperative echocardiography should be performed.
3. Postoperative aspirin or clopidogrel should be administered.
4. Patients should be discharged on a regimen of beta-blockers.
5. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.

18. Pulmonary Autograft (Ross Procedure)—Recommendations

Class I

1. The Ross procedure is recommended in infants and small children for whom no satisfactory alternative valve substitute exists. (Level of evidence C)

Class IIb

1. The Ross procedure may be considered in older children and young adults because of low operative risk, but patients and their families must be informed of the possible need for reoperation which increases over time. (Level of evidence C)

Class III

1. The Ross procedure is not recommended for middle-aged or older adults when suitable alternatives

to autograft replacement of the aortic valve are available with comparable results and without the need for replacement of the right ventricular outflow tract, because the latter adds the additional risk of pulmonary valve dysfunction and subsequent replacement. (Level of evidence C)

2. The Ross procedure is not recommended for patients with bicuspid valves and AR or aortic dilation if other alternatives are available. (Level of evidence C)

Quality Measures

1. Patients aged 45 years or more or patients who are younger with risk factors for CAD undergoing the Ross procedure should have preoperative coronary artery angiography.
2. Patients undergoing the Ross procedure should be counseled about the risk for reoperation on both the pulmonary autograft and the pulmonary homograft.
3. Annual TTE should be performed to monitor the size of the aortic root and ascending aorta and the function of the autograft and homograft valves.
4. Appropriate prophylaxis against endocarditis should be performed for invasive procedures.
5. ACE inhibitor drug therapy should be considered for patients with low EF postoperatively.

19. Balloon Aortic Valvuloplasty—Recommendations

Class IIa

1. Balloon aortic valvuloplasty can be useful as bridge to AVR in hemodynamically unstable adult patients with severe AS when immediate AVR is not feasible. (Level of evidence C)
2. BAV should be considered for patients with contra indications to AVR who can potentially be bridged to AVR or TAVR in the future. (Level of evidence C)
3. BAV should be considered in severely symptomatic patients with multiple comorbidities where contribution of AS to symptomatology such as chronic pulmonary disease or poor LV function, remains unclear. (Level of evidence C)

Class IIb

1. BAV may be reasonable in severely symptomatic patients where AVR is not an option for symptom relief. (Level of evidence C)
2. BAV may be considered in patients with symptomatic severe AS who require urgent major noncardiac surgery. (Level of evidence C)
3. BAV may be considered as a palliative measure in individual cases when surgery is contraindicated because of severe comorbidities. (Level of evidence C)
4. Hemodynamic assessment including cardiac output, aortic, LV and pulmonary pressures may be

considered before, during, and after the procedure. (Level of evidence C)

5. Rapid ventricular pacing may be performed to stabilize balloon during inflation unless self-seating dumbbell-shaped or other specifically designed balloons are available that do not require pacing. (Level of evidence C)

Quality Measures

1. Candidacy for AVR should be thoroughly assessed in collaboration with cardiac surgery.
2. Assessment of annular diameter and preprocedural AR should be carefully made with appropriate imaging.
3. Vascular access should be carefully evaluated with angiography before insertion of the closure device and a large sheath.
4. Stepwise dilation of the aortic valve can be used to achieve desired hemodynamic improvement.
5. Hemodynamic monitoring during BAV should include aortic diastolic pressure, LV filling pressures, and cardiac output.
6. Procedural outcomes with special attention to groin complications, AR, and procedural mortality should be monitored.
7. Patients should be monitored for the rate at which the patients are bridged to surgical AVR or TAVR.

20. TAVR With the Balloon-Expandable Valve—Recommendations¹

Class I

1. Evaluation for TAVR should be performed by a multidisciplinary team and panel [75, 108]. (Level of evidence A)
2. TAVR should be performed by a multidisciplinary cardiovascular and cardiac surgery team [75, 108]. (Level of evidence A)
3. If available as part of a research protocol or after Food and Drug Administration (FDA) approval, transfemoral AVR is recommended in inoperable patients provided they have an expected survival of greater than 1 year [75]. (Level of evidence A)
4. If available as part of a research protocol or after FDA approval, transfemoral, transaortic, transaxillary, or transapical AVR with the BAV can be considered for patients who are operative candidates and have a predicted surgical mortality greater than 15% and an STS risk score greater than 10% by two independent surgical assessments [108]. (Level of evidence A)
5. TAVR should be performed in a hybrid operating or catheterization room dedicated to the procedure and not with mobile C-arms [75, 108]. (Level of evidence B)

¹The self-expanding nitinol bioprosthesis is currently available in Europe and is under investigation in the US pivotal trials, but US recommendations are not available.

Class III

1. Transfemoral aortic valve implantation with a balloon-expandable valve should not be performed in patients who are not at high risk for conventional surgery. (Level of evidence C)
2. Transfemoral aortic valve implantation with a balloon-expandable valve should not be performed in patients who have other comorbidities that limit 1-year survival or who are extremely frail, limiting the likelihood of functional recovery after TAVR. (Level of evidence C)

Quality Measures

1. Patients being considered for TAVR should have surgical assessment by a multidisciplinary team including two independent surgeons to determine operative risk. Objective measures of risk such as the European System for Cardiac Operative Risk Evaluation and the STS risk score should be used to document risk but should not be used independent of a surgical assessment.
2. Patients being considered for TAVR will need a thorough preoperative assessment including TTE, diagnostic catheterization, pulmonary function tests, and CT scan.
3. Asymptomatic mild or moderate CAD does not need to be treated before TAVR. Clinically significant CAD that would impact the safety of TAVR procedure should be revascularized before valve implantation.
4. Vascular access should be assessed by iliac and femoral angiography as well as CT angiography. In patients with renal insufficiency, vessel anatomy can be assessed by intravascular ultrasonography and noncontrast CT. All studies should be reviewed by the physicians responsible for potential vascular repair.
5. Intraprocedural TEE should be employed to assist with TAVR planning, valve positioning, and valve assessment after deployment.
6. TAVR procedures should be performed by a cardiovascular medicine and cardiac surgery multidisciplinary team with extensive experience with high-risk valve surgery and percutaneous coronary interventions and balloon valvuloplasty.
7. Patients should be followed with annual TTE to assess valve function and monitor PVAR.
8. Patients should continue on a regimen of clopidogrel for 3 to 6 months and aspirin indefinitely after TAVR. In patients with atrial fibrillation, aspirin and warfarin should be continued indefinitely if feasible.
9. All centers performing TAVR should report their results to a national database.
10. Procedure time, fluoroscopy time, transfusion requirements, use of cardiopulmonary bypass, number of valves placed, need for sternotomy or conversion to conventional surgery, vascular

complications, and amount of contrast used should be measured for all cases.

11. Patients should be given routine antibiotic prophylaxis for all invasive procedures and routine dental work.

21. Transapical Aortic Valve—Recommendations

Class I

1. Transapical insertion of a balloon expandable aortic valve is recommended in patients with symptomatic severe AS who are considered to be at excessive risk for conventional AVR and are not candidates for a transfemoral approach owing to preexisting peripheral vasculature disease, and who have an expected survival of at least 1 year [108]. (Level of evidence B)
2. Evaluation for TAVR should be performed by a multidisciplinary team and panel [75, 108]. (Level of evidence A)
3. TAVR should be performed by a multidisciplinary cardiovascular and cardiac surgery team with extensive experience with high-risk valve surgery and percutaneous coronary interventions and balloon valvuloplasty [75, 108]. (Level of evidence A)
4. If available as part of a research protocol or after FDA approval, transfemoral, transaortic, transaxillary, or transapical AVR with the balloon expandable valve can be considered for patients who are operative candidates and have a predicted surgical mortality greater than 15% and an STS risk score greater than 10% by two independent surgical assessments [108]. (Level of evidence A)
5. TAVR should be performed in a hybrid operating or catheterization room dedicated to the procedure and not with mobile C-arms [75, 108].

Class IIa

1. Transapical insertion of a balloon expandable aortic valve may be a reasonable alternative in patients with critical AS who have an estimated mortality of at least 15% as independently judged by two cardiothoracic surgeons, or who have a predicted risk of mortality using the STS-PROM algorithm of 10% or greater, and who do not have access for the transfemoral approach. The PARTNER A trial was not powered to access noninferiority. (Level of evidence C)

Class III

1. Transapical insertion of a balloon expandable aortic valve is not recommended in low-risk patients with critical AS who are considered good candidates for conventional valve replacement. (Level of evidence C)

Quality Measures

1. All patients referred for transapical TAVR, should be evaluated by multidisciplinary team and two

cardiothoracic surgeons to determine suitability for conventional valve surgery.

2. All patients being considered for transapical TAVR should have a preoperative left heart catheterization, TTE, pulmonary function tests, and a CT scan of the chest, abdomen, and pelvis through the femoral heads.
3. Intraoperative TEE should be used in addition to fluoroscopy to adequately position the valve for deployment.
4. Procedure time, fluoroscopy time, transfusion requirements, use of cardiopulmonary bypass, number of valves placed, need for sternotomy or conversion to conventional surgery, vascular complications, and amount of contrast used should be measured for all cases.
5. Patients should be placed on a regimen of double antiplatelet agents for at least 3 to 6 months unless contraindicated, and aspirin indefinitely after the procedure.
6. All patients should have a yearly TTE and physical examination.
7. Patients should be given routine antibiotic prophylaxis for all invasive procedures and routine dental work.
8. Patients should be enrolled in a national registry database.

22. Remodeling—Recommendations

Class I

1. Aortic valve repairs should be checked by intraoperative TEE after the repair is completed. (Level of evidence C)
2. Patients should be followed postoperatively by yearly echocardiograms after aortic valve repair. (Level of evidence C)

Class IIa

1. Root remodeling may be considered for patients with significantly dilated roots and bicuspid valves or patients with acute aortic dissection, including excision of the noncoronary sinus as a remodeling procedure, also known as the Wolfe procedure. (Level of evidence C)

Class III

1. Root remodeling should be avoided in patients with connective tissue disorders. (Level of evidence C)

Quality Measures

1. Perioperative Gram-positive and Gram-negative antibiotic coverage.
2. Intraoperative transesophageal echocardiography should be performed.
3. Postoperative beta-blockers should be used.

23. Reimplantation—Recommendations

Class I

1. Root size, particularly at the sinuses of Valsalva should be measured by CT or MRI using the external diameter at its greatest extent. TEE is conventionally used to measure the internal diameter at its greatest extent, usually from sinus to sinus [3]. (Level of evidence B)
2. Intraoperative TEE is recommended to check the repair. (Level of evidence C)
3. Reimplantation is recommended for young patients, when feasible, who have aortic root dilation, with or without regurgitation, and a tricuspid aortic valve. (Level of evidence C)
4. An aortic root greater than 5.0 cm is recommended as a threshold for prophylactic repair for most patients, including patients with Marfan syndrome. (Level of evidence C)
5. For a patient with a family history of aortic dissection and Marfan syndrome, surgery is recommended at a size of 4.5 cm in cross-sectional diameter. (Level of evidence C)
6. Gram-positive and Gram-negative prophylactic antibiotics should be administered at the time of surgery. (Level of evidence C)
7. The patient should have yearly echocardiograms. (Level of evidence C)
8. Prophylactic antibiotics for any invasive procedure including dentistry are recommended. (Level of evidence C)

Class IIa

1. For patients with Loeys-Dietz syndrome, a threshold of 4.2 cm maybe considered for surgery. (Level of evidence C)
2. The cross-sectional area of the root in square centimeters divided by the patient's height in meters and exceeding 10 may be considered an indication for surgery. (Level of evidence C)
3. In female patients with a connective tissue disorder who are considering pregnancy, a prophylactic repair may be considered when the aortic root exceeds 4.0 cm. (Level of evidence C)
4. An antiplatelet agent should be considered postoperatively. (Level of evidence C)

Quality Measures

1. Prophylactic Gram-positive and Gram-negative coverage should be used at the time of surgery.
2. Intraoperative echocardiography.
3. Postoperative aspirin or Plavix should be administered.
4. Discharge should be on a regimen of beta-blockers.
5. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.
6. Patients should be given prophylactic antibiotics at any time that an invasive procedure is done, including dental procedures.

24. Bicuspid Valve Repair With or Without Aortic Tube Graft Replacement—Recommendations

Class I

1. All patients undergoing bicuspid repair should undergo intraoperative TEE. (Level of evidence C)
2. Prophylactic antibiotics including both Gram-positive and Gram-negative coverage should be used for patients undergoing bicuspid valve repair. (Level of evidence C)
3. Postoperative beta-blockers should be considered after bicuspid valve repairs. (Level of evidence C)
4. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively. (Level of evidence C)
5. Patients should be given prophylactic antibiotics at any time that an invasive procedure is done, including dental procedures, after a bicuspid valve repair. (Level of evidence C)

Quality Measures

1. Prophylactic antibiotics for both Gram-negative and Gram-positive coverage for the operative procedure.
2. Intraoperative echocardiography.
3. Postoperative beta-blockers and calcium-channel blockers.
4. Patients should be given prophylactic antibiotics at any time that an invasive procedure is done, including dental procedures.

25. Management of Acute Aortic Root and Ascending Aortic Dissection—Recommendations

Class I

1. Timely diagnosis is recommended utilizing cross-sectional imaging techniques or TEE. The latter can be performed in the operating room before sternotomy if needed to confirm the diagnosis [3]. (Level of evidence B)
2. Ascending aortic replacement (including resection of primary aortic tear) should be performed for patients with acute type A aortic dissection [3]. (Level of evidence B)
3. An open distal anastomotic, hemiarch, or total arch replacement technique is effective for the distal reconstruction of an acute type A dissection [3]. (Level of evidence B)
4. Ascending aortic and aortic arch replacement is indicated for patients with acute type A aortic dissection and a primary or secondary tear within the arch that involves or extends beyond the left common carotid arterial ostium with marked dilation of the aortic arch (>50 mm). (Level of evidence C)
5. Aortic root replacement is indicated for patients with acute type A aortic dissection and a primary tear that extends or originates in the left or right coronary sinuses or marked dilation (>45 mm) of the aortic root below the sinotubular junction. (Level of evidence C)

6. Arterial inflow cannulation for cardiopulmonary bypass during type A dissection repair should perfuse the true lumen directly. (Level of evidence C)
7. Long-term radiological surveillance after aortic dissection with or without surgical reconstruction should be performed at regular intervals of at least every 6 months for the first year, and then annually. (Level of evidence C)
8. Long-term annual echocardiographic surveillance is recommended for patients in whom an aortic valve-preserving reconstruction or bioprosthetic valve replacement was performed. (Level of evidence C)

Class IIa

1. It is reasonable to use antegrade brain perfusion or retrograde brain perfusion with hypothermic circulatory arrest to complete aortic arch reconstructions to reduce neurologic complications [3]. (Level of evidence B)
2. It is reasonable to utilize either an aortic valve-sparing or valve-replacement strategy when managing acute type A dissection if an acceptable low mortality rate can be achieved [3]. (Level of evidence B)
3. It is reasonable to treat acute type A intramural hematoma with urgent surgical intervention [3]. (Level of evidence B)
4. Use of intraoperative TEE is encouraged [3]. (Level of evidence B)
5. Postoperative, lifelong cross-sectional radiologic surveillance is reasonable for patients with residual aortic dissecting beyond the replaced aortic segment. (Level of evidence C)

Class IIb

1. Medical management and longitudinal surveillance may be considered to treat high-risk patients with asymptomatic, radiologically stable type A intramural hematoma. (Level of evidence C)
2. Medical management and longitudinal surveillance may be considered in patients with type B dissections involving the aortic arch. (Level of evidence C)
3. Annual echocardiography may be considered for type A aortic dissection patients in whom the aortic valve was resuspended, preserved, or replaced with a bioprosthesis. (Level of evidence C)

Quality Measures

1. Prophylactic perioperative antibiotics should be given for 24 to 48 hours at the surgeon's discretion.
2. Patients should be discharged on beta-blocker therapy.
3. Patients with concomitant CAD should be discharged on oral antiplatelet therapy.
4. Patients with concomitant CAD should be discharged on drug therapy for lowering low-density lipoprotein cholesterol.
5. ACE inhibitor drug therapy should be considered in patients with low EF postoperatively.

26. Ascending Aorta and Aortic Arch—Recommendations

Class I

1. All patients with suspected thoracic aortic disease on the basis of family history, symptoms, or physical examination should have the entire thoracic aorta imaged. (Level of evidence C)
2. All patients with a bicuspid aortic valve should undergo imaging of the thoracic aorta (3). (Level of evidence B)
3. All patients with Marfan syndrome or Loeys-Dietz syndrome or mutations associated with aortic disease or dissection should have the entire aorta imaged and appropriate blood testing performed for genetic mutations [3]. (Level of evidence B)
4. First-degree relatives of young patients with a bicuspid aortic valve or genetic mutation associated with aortic disease of the thoracic aorta should be advised to be further investigated. (Level of evidence C)
5. All patients for whom planned elective valvular surgery is planned and who have associated thoracic aortic disease should undergo preoperative cardiac catheterization [3]. (Level of evidence B)
6. Additional testing to quantitate a patient's comorbid status and develop a risk profile is recommended. These tests may include, for particularly high-risk patients, CT of the chest if not already done, pulmonary function tests, 24-hour electrocardiograph Holter, noninvasive carotid screening, brain imaging, echocardiography, neurocognitive testing, and assessment of degree of frailty. (Level of evidence C)
7. Intraoperative TEE is recommended for all patients undergoing surgery for thoracic aortic disease. (Level of evidence C)
8. Surgical repair is recommended when the ascending aorta or aortic root exceeds 5.5 cm if the patient has no genetically based aortic disease and is otherwise a suitable candidate for surgery [3]. (Level of evidence B)
9. Patients with genetically associated aortic diseases, including those with a bicuspid aortic valve, should undergo surgery at diameters exceeding 5.0 cm unless a family history of aortic dissection is present, then it is acceptable to lower the threshold to 4.5 cm. Alternatively, patients with a maximal ascending aortic area (IIr^2 , cm^2) to height in meters ratio exceeding 10 should be considered for surgery [3]. (Level of evidence B)
10. Patients with a growth rate exceeding 0.5 cm per year should be recommended to undergo surgery if no other limitations apply [3]. (Level of evidence B)
11. For patients with Loeys-Dietz syndrome or confirmed TGFBR1 or TGFBR2 mutation should be evaluated for repair of the aorta when the diameter exceeds 4.2 cm. (Level of evidence C)
12. For patients undergoing cardiac surgery other than for aortic indications, aortic repair is recom-

mended when diameter exceeds 4.5 cm (3). (Level of evidence B)

13. Aortic diameters should be measured at right angles to the axis of flow, which requires the use of 3-dimensional reconstructive software. The maximal diameters at each segment of the aorta should be reported. Echocardiography measures internal diameters while CT and MRI measures external diameters, and thus some allowance should be made for echocardiographic measurements being smaller. (Level of evidence C)
14. Separate valve and ascending aortic replacement are recommended for patients without significant aortic root dilation, for elderly patients, or for young patients with minimal dilation in whom a biological valve is being inserted or a bicuspid valve is being repaired [3]. (Level of evidence B)
15. Patients with Marfan, Loeys-Dietz, and Ehlers-Danlos syndromes and root dilation should undergo excision of the sinuses in combination with a modified David valve reimplantation procedure if technically feasible, or insertion of a valve graft conduit [3]. (Level of evidence B)
16. For more complicated arch reconstructions requiring extended periods of circulatory arrest, use of adjunctive brain perfusion techniques is recommended [3]. (Level of evidence B)

Class IIa

1. Regular echocardiography and MRI or CT evaluation after repair of thoracic aortic disease are reasonable. (Level of evidence C)

Quality Measures

1. Prophylactic antibiotics for both Gram-negative and Gram-positive coverage should be administered for the operative procedure.
2. Intraoperative TEE is recommended for all patients.
3. All patients with a bicuspid aortic valve, Marfan, Loeys-Dietz and Ehlers-Danlos syndromes, and a history consistent with familial thoracic aortic disease in first-degree relatives should undergo imaging of the aorta.
4. MRI or CT evaluation should be considered after surgical repair.
5. ACE inhibitor therapy should be considered in patients with low EF postoperatively.

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